

**UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

GEORGE BOURNAZIAN, Derivatively and  
on Behalf of CEMPRA, INC.,

Plaintiff,

v.

PRABHAVATHI FERNANDES, MARK  
HAHN, DAVID W. OLDACH, P. SHERRILL  
NEFF, RICHARD KENT, DOV GOLDSTEIN,  
GARHENG KONG, JOHN H. JOHNSON,  
DAVID GILL, MICHAEL R. DOUGHERTY,  
AND DAVID ZACCARDELLI,

Defendants,

and

CEMPRA, INC.,

Nominal Defendant.

CASE NO.

**PLAINTIFF'S VERIFIED  
SHAREHOLDER DERIVATIVE  
COMPLAINT**

**JURY TRIAL DEMANDED**

Plaintiff George Bournazian (“Plaintiff”), by his undersigned attorneys, derivatively and on behalf of Nominal Defendant Cempra, Inc. (“Cempra” or the “Company”), files this Verified Shareholder Derivative Complaint against Defendants Prabhavathi Fernandes, Mark Hahn, David W. Oldach, P. Sherrill Neff, Richard Kent, Dov Goldstein, Garheng Kong, John H. Johnson, David Gill, Michael R. Dougherty, and David Zaccardelli (collectively, the “Individual Defendants”) for breaches of their fiduciary duties as directors, officers, and/or controlling shareholders of Cempra, unjust enrichment, waste of corporate assets, abuse of control, gross mismanagement, and violations of Section 14(A) of the Securities Exchange Act of 1934 (the “Exchange Act”). As for his complaint against the Defendants, Plaintiff alleges the following

based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of Cempra's and the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Cempra, news reports, securities analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

#### **NATURE OF THE ACTION**

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Cempra's directors and officers from at least July 7, 2015 through the present (the "Relevant Period").

2. Cempra is a clinical-stage pharmaceutical company focused on developing differentiated antibiotics for the acute care and community settings to meet critical medical needs in the treatment of bacterial infectious diseases, particularly respiratory tract infections and staphylococcal infections. Its lead product, solithromycin (CEM-101), is being developed in oral capsules, intravenous, or IV, and suspension formulations, for the treatment of community-acquired bacterial pneumonia ("CABP"), one of the most serious infections of the respiratory tract in adults and children, as well as for the treatment of gonorrhea and other indications.

3. During the Relevant Period, the Company was in the late stages of its clinical development program of solithromycin to treat CABP. Phase 1 and Phase 2 studies for solithromycin had been completed prior to or were otherwise ongoing during the Relevant Period, and Phase 3 studies of solithromycin were completed prior to the Relevant Period.

4. A significant issue facing the development of solithromycin is damage to the liver, which can manifest in alanine aminotransferase (“ALT”) and aspartate transaminase (“AST”), liver enzymes that are indicators of liver damage or injury. An additional concern is “hepatotoxicity,” which implies chemical-driven liver damage.

5. Throughout the Relevant Period, in breach of their fiduciary duties, the Individual Defendants caused the Company to issue materially false and misleading statements, or to fail to disclose, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST, and (4) the Company’s disclosure controls and procedures and internal controls over financial reporting were not effective. The Individual Defendants knew or should have known, or recklessly disregarded the truth concerning the above facts.

6. When the truth was revealed, it was not even by the Company but the U.S. Food and Drug Administration (“FDA”). On November 2, 2016, the FDA posted a preliminary review of solithromycin on its website, which revealed, *inter alia*, that “[a] significant safety signal for hepatotoxicity was observed in the solithromycin development program,” and that there was a concern with “the high rate of infusion site-related reactions.”

7. As a result of this disclosure, shares of Cempra stock plummeted \$11.35, or 60.86%, to close at \$7.30 on November 2, 2016, a new 52-week low for the stock.

8. At a November 4, 2016 meeting with the Company, the FDA meticulously detailed the obvious truth about solithromycin causing hepatotoxicity and infusion-related reactions. The FDA presented proof based on preclinical and clinical data, both of which should have put the Individual Defendants on notice of the harsh reality.

9. Throughout the Relevant Period, in breach of their fiduciary duties, the Individual Defendants recklessly managed the Company by continuing the clinical trials even though they knew or should have known that patients were subject to dangerous levels of hepatotoxicity and infusion-related reactions but were not informed of such.

10. Additionally, in breach of their fiduciary duties, the Individual Defendants failed to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls over financial reporting.

11. Moreover, the Individual Defendants serving as members of the Board of Directors (the “Board”) approved an extravagant severance package for its former Chief Executive Officer (“CEO”) which constituted a breach of their fiduciary duties, waste of corporate assets, and unjust enrichment as to the former CEO based on the former CEO’s involvement in and lack of oversight over the wrongdoing discussed herein.

12. In light of the Defendants’ misconduct, which has subjected Cempra, its former CEO, its Chief Financial Officer (“CFO”), and its Chief Medical Officer (“CMO”) to being named as defendants in a consolidated federal securities fraud class action lawsuit pending in the United States District Court for the Middle District of North Carolina (the “Securities Fraud Class Action”), the need to undertake internal investigations, the need to implement adequate internal controls over its financial reporting, the losses from the waste of corporate assets, the losses due to the unjust enrichment of Defendants who were improperly over-compensated by

the Company and/or who benefitted from the wrongdoing alleged herein, the Company will have to expend many millions of dollars.

13. In light of the breaches of fiduciary duty engaged in by the Defendants, most of whom are the Company's current directors, their collective engagement in fraud, the substantial likelihood of the directors' liability in this derivative action and certain of them in the Securities Fraud Class Action, and their not being disinterested and/or independent directors, a majority of the Board cannot consider a demand to commence litigation against themselves on behalf of the Company with the requisite level of disinterestedness and independence.

#### **JURISDICTION AND VENUE**

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1) and Rule 14a-9 of the Exchange Act, 17 C.F.R. § 240.14a-9, and raise a federal question pertaining to the claims made in the Federal Securities Class Actions based on violations of the Exchange Act. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. §1367(a).

15. This derivative action is not a collusive action to confer jurisdiction on a court of the United States that it would not otherwise have.

16. Venue is proper in this District because the Defendants have conducted business in this District, and Defendants actions have had an effect in this District.

## **PARTIES**

### **Plaintiff**

17. Plaintiff is a current shareholder of Cempra common stock. Plaintiff purchased Cempra common stock in July 2015 and has continuously held Cempra common stock since then.

### **Nominal Defendant Cempra**

18. Nominal Defendant Cempra is a Delaware corporation with its principal executive offices at 6320 Quadrangle Drive, Suite 360, Chapel Hill, NC 27517. Cempra stock traded on the Nasdaq Global Market (“NASDAQ”) under the ticker symbol “CEMP.”

19. Cempra has two subsidiaries, Cempra Pharmaceuticals, Inc. and CEM-102 Pharmaceuticals, Inc.

### **Defendant Fernandes**

20. Defendant Prabhavathi Fernandes, Ph.D. (“Fernandes”), one of Cempra’s founders, was the Company’s President and CEO and a member of its Board since the Company’s founding in November 2005 until she retired on December 9, 2016. According to the Company’s Schedule 14A filed with the SEC on April 6, 2016 (the “2016 Proxy Statement”), as of February 29, 2016, Defendant Fernandes beneficially owned 849,508 shares of Cempra stock, 1.7% of the outstanding stock of the Company. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Fernandes beneficially owned over \$22.27 million worth of Company stock during the Relevant Period.

21. For the fiscal year ended December 31, 2015, Defendant Fernandes received \$2,777,619 in compensation from the Company, on a \$510,000 salary. This included \$762,147 in cash and \$2,015,472 in stock.

22. The 2016 Proxy Statement stated the following about Defendant Fernandes:

***Prabhavathi Fernandes, Ph.D.*** – Dr. Fernandes, one of our founders, has been our President and Chief Executive Officer and a member of our Board since our founding in November 2005. Prior to that, she was President and Chief Executive Officer of several privately held companies, including DarPharma, Inc. from 2003 to 2005, Ricerca Biosciences from 2000 to 2003 and Small Molecule Therapeutics from 1998 to 2000. Dr. Fernandes was Vice President, Drug Discovery of Bristol-Myers Squibb Company from 1988 to 1998, Senior Director of Squibb Pharmaceutical Research Institute from 1987 to 1988, Senior Project Leader of Abbott Laboratories from 1983 to 1987 and Senior Microbiologist of the Squibb Institute for Medical Research, the research division of E.R. Squibb and Sons, from 1980 to 1983. She has served on the advisory board of Optimer Pharmaceuticals, Inc. since 2004 and the supervisory board of GPC Biotech AG from 2004 to 2008. Dr. Fernandes served on the product development working group for Biodefense for the National Institute of Allergy and Infectious Diseases from 2003 to 2004 and the U.S. Congressional Panel for Assessment of Impact of Antibiotic Resistant Bacteria and the American Society for Microbiology Advisory Panel for Antibiotic Resistance from 1991 to 1995. Dr. Fernandes holds a B.S. in botany, zoology and chemistry from the University of Bangalore (India), an M.S. in microbiology from the Christian Medical College (India) and a Ph.D. in microbiology from Thomas Jefferson University, Philadelphia, Pennsylvania. Among other experience, qualifications, attributes and skills, Dr. Fernandes' experience in senior leadership roles in small and large pharmaceutical organizations and her position as President and Chief Executive Officer of our company led to the conclusion of our Board that she should serve as a director of our company in light of our business and structure.

### **Defendant Hahn**

23. Defendant Mark Hahn (“Hahn”) has been the Company’s Executive Vice President and Chief Financial Officer since February 2010. According to the 2016 Proxy Statement, as of February 29, 2016, Defendant Hahn beneficially owned 187,786 shares of Cempra stock. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Hahn beneficially owned over \$4.9 million worth of Company stock during the Relevant Period.

24. For the fiscal year ended December 31, 2015, Defendant Hahn received \$1,175,420 in compensation from the Company, on a \$350,000 salary. This included \$475,465 in cash and \$699,955 in stock.

25. The Company's annual report for the year ended December 31, 2015 stated the following about Defendant Hahn:

Mr. Hahn has been our Executive Vice President and Chief Financial Officer since February 2010. From 2008 to 2009, Mr. Hahn was the Chief Financial Officer of Athenix Corp., an agricultural biotechnology company, leading its merger with Bayer CropScience, where he served as Finance Director into 2010. Mr. Hahn has been the chief financial officer of various companies including GigaBeam Corporation, a telecommunications equipment company, from 2007 to 2008; BuildLinks, Inc., a software company, from 2002 to 2007; PerformaWorks, Inc., a software company, from 2001 to 2002; and Charles & Colvard, Ltd., a consumer products company, from 1996 to 2001. Mr. Hahn also served in various capacities, culminating in Senior Manager, at Ernst & Young and its predecessors from 1984 until 1996. Mr. Hahn holds a B.B.A. in accounting and finance from the University of Wisconsin-Milwaukee and is a certified public accountant in the State of Maryland and North Carolina.

#### **Defendant Oldach**

26. Defendant David W. Oldach ("Oldach") has been the Company's CMO since January 2015. According to the 2016 Proxy Statement, as of February 29, 2016, Defendant Oldach beneficially owned 77,400 shares of Cempra stock. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Oldach beneficially owned over \$2.0 million worth of Company stock during the Relevant Period.

27. For the fiscal year ended December 31, 2015, Defendant Oldach received \$754,537 in compensation from the Company, on a \$300,000 salary. This included \$407,300 in cash and \$347,237 in stock.

28. The Company's website, [www.cempra.com](http://www.cempra.com), stated the following about Defendant Oldach:

David Oldach joined Cempra Pharmaceuticals in 2011. Between 2006 and 2011, Dr. Oldach directed clinical research at Gilead Sciences, Inc., where his drug development experience ranged from IND/first-in-human trial development and execution through NDA-supportive Phase 3 protocol development and execution. Dr. Oldach received his Medical Degree, Magna Cum Laude, from the University of Maryland School of Medicine and completed a residency in Internal Medicine at the Massachusetts General Hospital. He completed an Infectious Disease Fellowship at Johns Hopkins University School of Medicine, serving under John Bartlett. His academic clinical research included studies in community-acquired pneumonia and surgical infections, as well as HCV pathogenesis. At the time of his transition from academic medicine to industry, Dr. Oldach was a tenured Associate Professor of Medicine at the University of Maryland School of Medicine and served as the Infectious Diseases Section Chief in the Baltimore Veterans Administration Hospital.

29. During the period of time when the Company materially misstated information to keep the stock price inflated, and before the scheme was exposed, Defendant Oldach made the following sales of Company stock (and made no purchases of Company stock). On November 9, 2015, Defendant Oldach sold 12,200 shares of Company stock for \$28.78 per share. On December 11, 2015, Defendant Oldach sold 8,222 shares of Company stock for \$30.33 per share. On December 15, 2015, Defendant Oldach sold 1,778 shares of Company stock for \$30.00 per share. Thus, before the fraud was exposed, he sold 22,200 Company shares on inside information, for which he received over \$653,829. His insider sales, made with knowledge of material non-public information before the material misstatements and omissions were exposed, demonstrate his motive in facilitating and participating in the fraud.

#### **Defendant Neff**

30. Defendant P. Sherrill Neff (“Neff”) has been a Company director since September 2011. Defendant Neff is a member of the Compensation Committee. According to the 2016 Proxy Statement, as of February 29, 2016, Defendant Neff beneficially owned 3,630,601 shares of Cempra stock, 7.5% of the outstanding stock of the Company. Given that the price per share

of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Neff beneficially owned about \$95.2 million worth of Company stock during the Relevant Period.

31. For the fiscal year ended December 31, 2015, Defendant Neff received \$266,459 in compensation from the Company. This included \$40,000 in cash fees and \$226,459 in stock awards.

32. The 2016 Proxy Statement stated the following about Defendant Neff:

**P. Sherrill Neff** – Mr. Neff has served on our Board since September 2011. Mr. Neff founded Quaker Partners Management, L.P. in 2002 and has since served as a partner at the investment firm. From 1994 to 2002, Mr. Neff was President and Chief Operating Officer of Neose Technologies, Inc., a biopharmaceutical company, and a director from 1994 to 2003. From 1993 to 1994, he was Senior Vice President, Corporate Development at U.S. Healthcare. Prior to that time, Mr. Neff was managing director at investment bank Alex Brown & Sons for nine years. Mr. Neff holds a B.A. from Wesleyan University and a J.D. from the University of Michigan Law School. Mr. Neff serves on the board of directors of Resource Capital Corporation, (NYSE: RSO), a publicly traded real estate investment trust, as well as the following privately held organizations: Intact Vascular, Inc. and RainDance Technologies, Inc. Mr. Neff also served on the board of directors of Amicus Therapeutics, Inc. from 1996 until 2011, Regado Biosciences, Inc. (NASDAQ: RGDO) from 2005 until 2015, and National Venture Capital Association from 2009 until 2014. Among other experience, qualifications, attributes and skills, Mr. Neff's experience in the venture capital industry led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

### **Defendant Kent**

33. Defendant Richard Kent, M.D. (“Kent”) has been a Company director since September 2010. Defendant Kent is a member of the Compensation Committee. According to the 2016 Proxy Statement, as of February 29, 2016, Defendant Kent beneficially owned 2,427,246 shares of Cempra stock, 5.0% of the outstanding stock of the Company. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Kent beneficially owned over \$63.64 million worth of Company stock during the Relevant Period.

34. For the fiscal year ended December 31, 2015, Defendant Kent received \$266,459 in compensation from the Company. This included \$40,000 in cash fees and \$226,459 in stock awards.

35. The 2016 Proxy Statement stated the following about Defendant Kent:

**Richard Kent, M.D.** – Dr. Kent has served on our Board since September 2010. Dr. Kent has been a partner at Intersouth Partners, a venture capital firm, since 2008. From 2002 to 2008, Dr. Kent was the President and Chief Executive Officer of Serenex, Inc., a drug development company, when it was acquired by Pfizer Inc. From 2001 until he joined Serenex, Dr. Kent was President and Chief Executive Officer of Ardent Pharmaceuticals, Inc. Before that, he held senior executive positions at GlaxoSmithKline plc., where he was Senior Vice President of Global Medical Affairs and Chief Medical Officer, at Glaxo Wellcome plc., where he was Vice President of U.S. Medical Affairs and Group Medical Director, and at Burroughs Wellcome plc., where he was International Director of Medical Research. Dr. Kent served as a director of Cytomedix, Inc. (now Nuo Therapeutics, Inc.), a publicly traded biopharmaceutical company, from 2012 through 2014, and served as a director of Inspire Pharmaceuticals, Inc. from 2004 to 2011. He also serves on the boards of several private companies. Dr. Kent holds a B.A. from the University of California, Berkley and an M.D. from the University of California, San Diego. Among other experience, qualifications, attributes and skills, Dr. Kent's knowledge and experience in the securities and investments industry and leadership roles in the pharmaceutical industry led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

### **Defendant Goldstein**

36. Defendant Dov Goldstein, M.D. (“Goldstein”) has been a Company director since January 2008. Defendant Goldstein is Chair of the Nominating and Governance Committee. According to the 2016 Proxy Statement, as of February 29, 2016, Defendant Goldstein beneficially owned 1,246,576 shares of Cempra stock, 2.6% of the outstanding stock of the Company. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Goldstein beneficially owned about \$32.7 million worth of Company stock during the Relevant Period.

37. For the fiscal year ended December 31, 2015, Defendant Goldstein received \$269,459 in compensation from the Company. This included \$43,000 in cash fees and \$226,459 in stock awards.

38. The 2016 Proxy Statement stated the following about Defendant Goldstein:

**Dov A. Goldstein, M.D.** – Dr. Goldstein has served on our Board since January 2008. He has been a Partner at Aisling Capital, a private investment firm, since 2008. From 2000 until its acquisition by Pfizer Inc. in 2005, Dr. Goldstein was Executive Vice President and Chief Financial Officer of Vicuron Pharmaceuticals, Inc. He led the valuation and financial due diligence for the merger with Biosearch Italia (Nuovo mercato: BIO.MI), the first U.S. and Italian public-to-public company merger. Prior to Vicuron Pharmaceuticals, Dr. Goldstein was Director of Venture Analysis at HealthCare Ventures, a privately held investment fund. Dr. Goldstein currently serves on the board of directors of ADMA Biologics, Inc. (NASDAQ: ADMA) and Esperion Therapeutics, Inc. (NASDAQ: ESPR). Dr. Goldstein has previously served on several company boards of directors, including those of Durata Therapeutics Inc. (acquired by Actavis PLC), Topaz Pharmaceuticals (acquired by Sanofi Pasteur S.A.), and Loxo Oncology, Inc. (NASDAQ:LOXO), where he was also Chief Financial Officer. Dr. Goldstein received his M.D. from Yale School of Medicine and completed an internship in the Department of Medicine at Columbia-Presbyterian Hospital. He received his M.B.A from the Columbia Business School and his B.S. with honors from Stanford University. Among other experience, qualifications, attributes and skills, Dr. Goldstein's knowledge and experience in the pharmaceutical industry and venture capital industry led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

39. During the period of time when the Company materially misstated information to keep the stock price inflated, and before the scheme was exposed, Defendant Goldstein made the following sale of Company stock (and made no purchases of Company stock). On January 4, 2016, Defendant Goldstein sold 842 shares of Company stock for \$30.07 per share. Thus, before the fraud was exposed, he sold 842 Company shares on inside information, for which he received over \$25,318. His insider sale, made with knowledge of material non-public information before the material misstatements and omissions were exposed, demonstrates his motive in facilitating and participating in the fraud.

### **Defendant Kong**

40. Defendant Garheng Kong, M.D., Ph. D. (“Kong”) has been a Company director since September 2006 and has served as the Company’s Chairman of the Board since November 2008. Defendant Kong also serves as Chair of the Compensation Committee and as a member of the Audit Committee. According to the 2016 Proxy Statement, as of February 29, 2016, Defendant Goldstein beneficially owned 109,614 shares of Cempra stock. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Goldstein beneficially owned about \$2.9 million worth of Company stock during the Relevant Period.

41. For the fiscal year ended December 31, 2015, Defendant Kong received \$356,751 in compensation from the Company. This included \$85,000 in cash fees and \$271,751 in stock awards.

42. The 2016 Proxy Statement stated the following about Defendant Kong:

***Garheng Kong, M.D., Ph.D.*** – Dr. Kong has served on our Board since September 2006 and as Chairman of our Board since November 2008. Dr. Kong has been the Managing Partner of Sofinnova Healthquest, a healthcare investment firm, since July 2013. He was a general partner at Sofinnova Ventures, a venture firm focused on life sciences, from September 2010 to December 2013. From 2000 to September 2010, he was at Intersouth Partners, a venture capital firm, most recently as a general partner, where he was a founding investor or board member for various life sciences ventures, several of which were acquired by large pharmaceutical companies. Dr. Kong has also served on the board of directors of Histogenics Corporation (NASDAQ: HSGX), a regenerative medicine company, since July 2012, Alimera Sciences, Inc. (NASDAQ: ALIM), a biopharmaceutical company, since October 2012, and has served on the board of Laboratory Corporation of America Holdings (NYSE: LH), a healthcare company, since December 2013. Dr. Kong holds a B.S. from Stanford University. He holds an M.D., Ph.D. and M.B.A. from Duke University. Among other experience, qualifications, attributes and skills, Dr. Kong’s knowledge and experience in the venture capital industry and his medical training led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

**Defendant Johnson**

43. Defendant John H. Johnson (“Johnson”) has been a Company director since June 2009. Defendant Johnson is a member of the Nominating and Governance Committee. According to the 2016 Proxy Statement, as of February 29, 2016, Defendant Johnson beneficially owned 103,784 shares of Cempra stock. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Johnson beneficially owned about \$2.7 million worth of Company stock during the Relevant Period.

44. For the fiscal year ended December 31, 2015, Defendant Johnson received \$266,459 in compensation from the Company. This included \$40,000 in cash fees and \$226,459 in stock awards.

45. The 2016 Proxy Statement stated the following about Defendant Johnson:

***John H. Johnson*** – Mr. Johnson has served on our Board since June 2009. He served as President and Chief Executive Officer of Dendreon Corp., a publicly traded biotechnology company (NASDAQ: DNDNJ), from February 2012, became Chairman in July 2013, and served in those roles until August 2014. He served as the Chief Executive Officer and as a director of Savient Pharmaceuticals, Inc., a company that develops and commercializes specialty pharmaceuticals, from 2011 to January 2012. Mr. Johnson was Senior Vice President of Eli Lilly and Company and President of Lilly Oncology, Eli Lilly’s oncology business unit, from 2009 to 2011. From 2007 to 2009, Mr. Johnson was Chief Executive Officer of ImClone Systems Incorporated, a biopharmaceutical development company, and was also a member of ImClone’s board of directors until it became a wholly owned subsidiary of Eli Lilly in 2008. From 2001 to 2007, Mr. Johnson served as company group chairman of Johnson & Johnson’s Worldwide Biopharmaceuticals unit. Mr. Johnson served as Chairman of the Board of Tranzyme, Inc. (NASDAQ: TZYM), a publicly traded biopharmaceutical company, from December 2010 until July 2013. Mr. Johnson serves as the chairman of the board of Cortendo AB, a global biopharmaceutical company, and also serves as a director of Sucampo Pharmaceuticals, Inc. (NASDAQ: SCMP), a global biopharmaceutical company, Portola Pharmaceuticals, Inc. (NASDAQ: PTLA), a biopharmaceutical company, and Histogenics Corporation (NASDAQ: HSGX), a regenerative medicine company. Mr. Johnson holds a B.S. in Education from East Stroudsburg University of Pennsylvania. Among other experience, qualifications, attributes and skills, Mr. Johnson’s leadership roles in large pharmaceutical organizations led to the

conclusion of our Board that he should serve as a director of our company in light of our business and structure.

**Defendant Gill**

46. Defendant David Gill (“Gill”) has been a Company director since April 2012. Defendant Gill is Chair of the Audit Committee. According to the 2016 Proxy Statement, as of February 29, 2016, Defendant Gill beneficially owned 75,000 shares of Cempra stock. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Gill beneficially owned about \$2 million worth of Company stock during the Relevant Period.

47. For the fiscal year ended December 31, 2015, Defendant Gill received \$276,459 in compensation from the Company. This included \$50,000 in cash fees and \$226,459 in stock awards.

48. The 2016 Proxy Statement stated the following about Defendant Gill:

***David Gill*** – Mr. Gill joined our Board in April 2012. Mr. Gill is Chief Financial Officer of EndoChoice Holdings, Inc. (NYSE: GI), a publicly traded medical device company, a position he has held since August 2014, and effective March 2016, he is also President and Chief Operating Officer. He served as the Chief Financial Officer of INC Research Holdings Inc (NASDAQ: INCR), a clinical research organization, from February 2011 to August 2013, and served as a board member and audit committee chairman of INC Research from 2007 to 2010. From March 2009 to February 2011, Mr. Gill was the Chief Financial Officer of TransEnterix, a then private medical device company. From July 2005 to November 2006, Mr. Gill was Chief Financial Officer and Treasurer of NxStage Medical, Inc. (NASDAQ: NXTM), a publicly traded dialysis equipment company. He currently serves as a director and chair of the audit committee of Histogenics Corporation (NASDAQ: HSGX), a regenerative medicine company, positions he has held since February 2015. From 2006 to 2011, he served on several public and private company boards of directors, including those of LeMaitre Vascular (NASDAQ: LMAT), a publicly traded medical device company, and IsoTis, Inc. (NASDAQ: ISOT), a publicly traded orthobiologics company that was acquired by Integra LifeSciences Holdings Corporation in October 2007. From January 2002 to May 2005, Mr. Gill served as Senior Vice President and Chief Financial Officer of CTI Molecular Imaging, Inc., (NASDAQ: CTMI) a publicly traded medical imaging company, until its sale to Siemens AG. Mr. Gill has led initial public offerings for three companies and has raised more than \$500

million in equity and \$600 million in debt over his career. Mr. Gill holds a B.S. degree, cum laude, in Accountancy from Wake Forest University and an M.B.A. degree, with honors, from Emory University. Mr. Gill was formerly a certified public accountant. Among other experience, qualifications, attributes and skills, Mr. Gill's education and experience in accounting and finance, and his service as an officer and as a director of various publicly traded companies led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

**Defendant Dougherty**

49. Defendant Michael R. Dougherty ("Dougherty") has been a Company director since May 2013. Defendant Dougherty is a member of the Audit Committee and Nominating and Governance Committee. According to the 2016 Proxy Statement, as of February 29, 2016, Defendant Dougherty beneficially owned 62,000 shares of Cempra stock. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Dougherty beneficially owned over \$1.6 million worth of Company stock during the Relevant Period.

50. For the fiscal year ended December 31, 2015, Defendant Dougherty received \$271,459 in compensation from the Company. This included \$45,000 in cash fees and \$226,459 in stock awards.

51. The 2016 Proxy Statement stated the following about Defendant Dougherty:

***Michael R. Dougherty*** – Mr. Dougherty joined our Board in May 2013. Mr. Dougherty has been Executive Chairman of Celator Pharmaceuticals, Inc. since August 2015. Mr. Dougherty was Chief Executive Officer, and Member of the Board of Directors, of Kalidex Pharmaceuticals, Inc. from May 2012 to October 2012. Mr. Dougherty was the President and Chief Executive Officer of Adolor Corp. (NASDAQ: ADLR) and a member of the Board of Directors of Adolor from December 2006 until December 2011. Mr. Dougherty joined Adolor as Senior Vice President of Commercial Operations in November 2002, and until his appointment as President and Chief Executive Officer in December 2006, served in a number of capacities, including Chief Operating Officer and Chief Financial Officer. From November 2000 to November 2002, Mr. Dougherty was President and Chief Operating Officer of Genomics Collaborative, Inc., a privately held functional genomics company. Previously, Mr. Dougherty served in a variety of senior positions at Genaera Corporation, formerly Magainin Pharmaceuticals Inc., a publicly-

traded biotechnology company, including as President and Chief Executive Officer, as well as a director, and at Centocor, Inc., a publicly-traded biotechnology company, including as Senior Vice President and Chief Financial Officer. Mr. Dougherty is currently on the board of directors of Biota Pharmaceuticals, Inc. (NASDAQ; BOTA), Trevena, Inc. (NASDAQ; TRVN) and Celator Pharmaceuticals, Inc. (NASDAQ; CPXX). Mr. Dougherty was a member of the board of directors of Viropharma Incorporated (NASDAQ; VPHM) from January 2004 to January 2014 when it was acquired by Shire Plc. Mr. Dougherty received a B.S. from Villanova University. Among other experience, qualifications, attributes and skills, Mr. Dougherty's leadership roles in small and large pharmaceutical organizations led to the conclusion of our Board that he should serve as a director of our company in light of our business and structure.

**Defendant Zaccardelli**

52. Defendant David Zaccardelli, Pharm.D. ("Zaccardelli") has been a Company director since August 11, 2016. On December 9, 2016, Defendant Zaccardelli was appointed the Company's Acting Chief Executive Officer, replacing Defendant Fernandes. He will be paid at the annual rate of \$540,000, will be eligible for an incentive bonus with a target bonus equal to 60% of his base salary. Additionally, he will receive 50,000 shares of Company stock that will fully vest on December 9, 2017 if he is still a Director or employed at the Company. Lastly, the Company will grant him 150,000 stock options. According to a Form 4 filed on behalf of Defendant Zaccardelli, as of August 12, 2016, Defendant Zaccardelli beneficially owned 25,000 shares of Cempra stock. Given that the price per share of Cempra common stock at the close of trading on September 28, 2016 was \$26.22, Zaccardelli beneficially owned \$655,500 worth of Company stock then.

53. The press release announcing Defendant Zaccardelli's appointment, issued on August 11, 2016, stated the following about him:

From 2004 until 2016, Dr. Zaccardelli served in several senior management roles at United Therapeutics, including chief operating officer, chief manufacturing officer and executive vice president, pharmaceutical development and operations. Prior to joining United Therapeutics, Dr. Zaccardelli founded and led a startup company focused on contract pharmaceutical development services, from 1997 through 2003. From 1988 to

1996, Dr. Zaccardelli worked at Burroughs Wellcome & Co. and Glaxo Wellcome, Inc. in a variety of clinical research positions. He also served as director of clinical and scientific affairs for Bausch & Lomb Pharmaceuticals from 1996 to 1997.

“David’s leadership at a company that successfully transformed from R&D into a highly profitable commercial pharmaceutical company, including his significant product development experience, will prove valuable to Cempra as we prepare to launch Solithera™ (solithromycin),” said Garheng Kong, M.D., Ph.D., chairman of Cempra.

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Dr. Zaccardelli received his doctor of pharmacy from the University of Michigan.

#### **FIDUCIARY DUTIES OF THE DEFENDANTS**

54. By reason of their positions as officers, directors, controlling shareholders, and/or fiduciaries of Cempra and because of their ability to control the business and corporate affairs of Cempra, the Individual Defendants owed Cempra and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Cempra in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Cempra and its shareholders so as to benefit all shareholders equally.

55. Each director and officer of the Company owes to Cempra and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligations of fair dealing.

56. The Defendants, because of their positions of control and authority as directors, officers, and/or controlling shareholders of Cempra, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

57. To discharge their duties, the officers and directors of Cempra were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

58. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Cempra, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also officers and directors of the Company has been ratified by the remaining Individual Defendants who collectively comprised Cempra's Board at all relevant times.

59. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants had a duty to prevent and not to effect the dissemination of, inaccurate and untruthful information with respect to, *inter alia*, the Company's financial condition, performance, growth, operations, financial statements, business, products, management, earnings, internal controls, and present and future business prospects, including the dissemination of false information regarding the toxicity of its drug product candidates so that the market price of the Company's common stock would be based upon truthful and accurate information.

60. To discharge their duties, the officers and directors of Cempra were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Cempra were required to, among other things:

- (a) Ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Delaware, North Carolina, the United States, and pursuant to Cempra's Code of Ethics and internal guidelines;
- (b) Conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;
- (c) Remain informed as to how Cempra conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;
- (d) Establish and maintain systematic and accurate records and reports of the business and internal affairs of Cempra and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;
- (e) Maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Cempra's operations would comply with all laws and Cempra's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;

(f) Exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;

(g) Refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) Examine and evaluate any reports of examinations, audits, or other information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

61. Each of the Defendants further owed to Cempra and its shareholders the duty of loyalty requiring that each favor Cempra's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence or knowledge of the affairs of the Company to gain personal advantage.

62. At all times relevant hereto, the Individual Defendants were the agents of each other and of Cempra and were at all times acting within the course and scope of such agency.

63. Because of their controlling, advisory, executive, managerial, and directorial positions with Cempra, each of the Individual Defendants had access to adverse, non-public information about the Company.

64. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Cempra.

#### **CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION**

65. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with

and conspired with one another in furtherance of their wrongdoing. The Individual Defendants caused the Company to conceal the true facts as alleged herein. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

66. The purpose and effect of the conspiracy, common enterprise, and/or common course of conduct was, among other things, to: (i) facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, and violations of Section 14(a) of the Exchange Act; (ii) to conceal adverse information concerning the Company's operations, competitiveness, future business prospects and internal controls; and (iii) to artificially inflate the Company's stock price while two of the Individual Defendants engaged in insider sales.

67. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company purposefully, recklessly, or negligently to conceal material facts, fail to correct such misrepresentations, and violate applicable laws. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein. Because the actions described herein occurred under the authority and approval of the Board, each of the Individual Defendants who is a director of Cempra was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

68. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each of the Individual Defendants acted with actual or constructive knowledge of the primary wrongdoing, either took direct part in, or

substantially assisted the accomplishment of, that wrongdoing, and was or should have been aware of his or her overall contribution to and furtherance of the wrongdoing.

69. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Cempra, and was at all times acting within the course and scope of such agency.

### **INDIVIDUAL DEFENDANTS' MISCONDUCT**

#### **Background**

70. Cempra is a clinical-stage pharmaceutical company focused on developing differentiated antibiotics for the acute care and community settings to meet critical medical needs in the treatment of bacterial infectious diseases, particularly respiratory tract infections and staphylococcal infections.

71. Of particular interest to the company is CABP. As represented by the Company, CABP is one of the most common serious infectious diseases of the respiratory tract and is the most frequent cause of death due to bacterial infections in the U.S. There are 1.6 million fatal cases of pneumococcal disease annually worldwide which is more than the deaths caused annually by breast or prostate cancer. There are approximately five to six million cases of CABP in the U.S. every year, approximately one million of which require hospitalization. Typical bacteria that cause CABP include *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis* and *Staphylococcus aureus*. These four bacteria account for approximately 85% of CABP cases. Other organisms, called atypical bacteria, may be involved in CABP and include *Legionella pneumophila*, *S. aureus*, *Chlamydophila pneumoniae* and *Mycoplasma pneumoniae*.

72. CABP and other respiratory tract infections can be treated with numerous classes of antibiotics, including macrolides, tetracyclines, fluoroquinolones, penicillins and cephalosporins. Each class has a different mechanism of action and resulting spectrum of activity. Each class, however, whether used alone or in combination, has limitations that can impede the treatment of CABP infections. Historically, macrolides have been among the most commonly prescribed drugs for respiratory tract infections because of their broad spectrum of activity and relative safety. Azithromycin, a second-generation macrolide which is sold as Zithromax and Z-PAK and as a generic drug, is the most widely prescribed macrolide with total U.S. prescriptions of 50 million in 2013, according to IMS New Prescription Audit.

73. Nevertheless, the Company has continuously represented that an unmet medical need existed with respect to the treatment of CABP because, *inter alia*, increased resistance and ***lack of tolerability*** to generic antibiotics have led to increased rates of hospitalization and a critical need for a safe and effective oral antibiotic for the treatment of CABP.

74. To fill this void, Cempra began development of its lead product, solithromycin (CEM-101), which is being developed in oral capsules, intravenous (“IV”), and suspension formulations, for the treatment of CABP, as well as for the treatment of gonorrhea and other indications.

75. The Company described solithromycin as a potent new fourth generation macrolide and the first fluoroketolide in clinical development. According to the Company, solithromycin has broad use potential against many types of infections and in many patient populations, including pediatrics and pregnancy. Further, solithromycin’s potency comes from its unique chemical structure, which provides greater ability to fight resistant bacteria.

76. The Company further represented that solithromycin has excellent organ and tissue distribution and intracellular activity, which allows it to reach bacteria at body sites that other antibiotics may not, and that solithromycin is active against most CABP pathogens, including pneumococcal strains resistant to other macrolides.

77. Importantly, the Company also represented, in its annual report for the year ended December 31, 2015 and filed with the SEC on February 25, 2016 (the “2015 10-K”), that the Company’s “pre-clinical and clinical studies to date have demonstrated solithromycin’s efficacy *and safety*” and that solithromycin has “key attributes” that “make it a safe and effective treatment for CABP.”<sup>1</sup>

#### **Pharmaceutical Drug Product Development and Solithromycin**

78. In the United States, pharmaceutical development and marketing is regulated by the FDA, an agency of the U.S. Department of Health and Human Services. The modern regulatory regime was enacted in 1962, after Thalidomide, a sleeping pill, caused birth defects in thousands of babies. In reaction to this tragedy, Congress passed the Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act (the “FDCA”) requiring that any company that wanted to market a pharmaceutical product in the United States (in industry parlance, a “sponsor”) had to obtain prior approval from the FDA, and that the approval had to be based upon substantial scientific evidence demonstrating that the product was safe and effective for its intended use in humans.

79. The FDCA, as amended, requires the Commissioner of the FDA to refuse any drug application if:

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<sup>1</sup> Unless otherwise noted, emphasis is added hereinafter.

(a) "he has insufficient information to determine whether such drug is safe for use under such conditions;" or

(b) "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof."

21 U.S.C. § 355(d)(4)-(5).

80. Prior to conducting any clinical research in humans, a sponsor must screen the proposed drug (or biologic) for toxicity with animal studies, and file an Investigational New Drug ("IND") application with the FDA. Although there are technically three types of INDs, virtually all drugs are developed under the standard development IND (also known as an investigator IND). An IND application includes the following information:

- animal pharmacology and toxicology studies sufficient to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Any previous experience with the drug in humans (such as use in foreign countries) also must be included.
- manufacturing information describing the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
- clinical protocols and investigator information including sufficient detail regarding the proposed protocols for clinical studies to assess whether the initial-phase trials will expose human subjects to unnecessary risks.

81. The sponsor must also commit to obtain *informed consent* from the research subjects, to obtain review of the study by a local institutional review board ("IRB"), and to adhere to the investigational new drug regulations. 21 C.F.R. § 312.23. After filing an IND, the sponsor must wait 30 days before commencing human clinical trials.

82. According to the Company's 2015 10-K, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

*Phase 1.* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

*Phase 2.* The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

*Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

(Italics in original.)

83. The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of a New Drug Application (“NDA”) requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

84. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product’s identity, strength, quality and purity.

85. Under the Food and Drug Administration Amendments Act of 2007 (“FDAAA”), all New Chemical Entities (“NCE”) prior to approval are referred to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions, unless the Secretary of Health and Human Services provides in the action letter on the drug application a summary of the reasons why it was not referred. An advisory

committee is a panel of experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee but it generally follows such recommendations.

86. Further, the FDA has four programs that are intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of a serious or life-threatening condition: (1) fast track designation, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation.<sup>2</sup>

87. In August 2015, the FDA granted Fast Track designation for IV and oral solithromycin for the treatment of CABP. As a result, the Company began to submit its NDA for solithromycin on a rolling basis as portions of the NDA became ready, rather than waiting for the entire NDA to be completed, which it believed would speed up the review time of the NDA.

88. Moreover, the FDA designated both oral and intravenous solithromycin as Qualified Infectious Disease Products (“QIDP”) for the indication of CABP. As a result of the QIDP designation, solithromycin is eligible for priority review by the FDA. Based on these factors, assuming FDA approval, the Company expected to be able to launch solithromycin for CABP in 2017.

89. The Company completed two pivotal Phase 3 trials for solithromycin to treat CABP. The first was a Phase 3 trial for oral solithromycin, which was designed based on FDA guidance documents and comments from the FDA, which the Company initiated in December 2012 and for which it announced positive topline results on January 5, 2015. In December 2013, the Company began the second Phase 3 trial to treat CABP with IV solithromycin progressing to

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<sup>2</sup> See *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics*, May 2014, <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf> (last accessed November 22, 2016).

oral solithromycin, for which it announced positive topline results on October 16, 2015. Based on the FDA draft guidelines and the Company's discussions with the FDA, it believed that these two Phase 3 trials would be sufficient to support its planned NDA for solithromycin to treat CABP. These trials were randomized, double-blinded studies using a respiratory fluoroquinolone, moxifloxacin (Avelox), for which Cempra had to show non-inferiority for efficacy and acceptable safety and tolerability. Moxifloxacin was selected as the comparator because it is administered at the same dose, 400 mg once a day worldwide, while levofloxacin, the respiratory fluoroquinolone used in Cempra's Phase 2 trial, is used at 750 mg once daily in the U.S. and 500 mg twice daily in the rest of the world. Being a global study, the same dose was required to be used in Cempra's Phase 3 trials. Non-inferiority for efficacy means solithromycin would have to prove it is statistically as effective as a comparator drug within a pre-defined margin.

90. On January 5, 2015, Cempra announced positive topline results from its global, pivotal Phase 3 clinical trial of solithromycin oral capsules in the treatment of patients with CABP. The Company reported that in the intent-to-treat or ("ITT"), population (which was all randomized patients), solithromycin met the primary objective of statistical non-inferiority (10% non-inferiority margin) of the early clinical response at 72 (-12/+36) hours after initiation of therapy compared to moxifloxacin. Cempra further reported that solithromycin also met the secondary objectives of non-inferiority in clinical success at the short term follow up ("SFU"), visit, 5-10 days after the end of therapy, both in the ITT and clinically evaluable populations. The point estimates for the primary endpoint of early clinical response were 78.2% for solithromycin and 77.9% for moxifloxacin. The 95% confidence interval for the treatment difference had lower and upper bounds of -5.5% and 6.1%, respectively. The results were

similar in the combined total patient population, however, initial sub-groups analysis by age, indicate that the difference in efficacy point estimates became larger with increases in patient age and favored solithromycin in the ITT early clinical response groups. The results for the secondary efficacy endpoints supported results from the primary endpoint.

91. In September 2015, the Company initiated two Phase 2 studies of the effectiveness of solithromycin as a treatment for non-alcholoic steatohepatitis (“NASH”) and chronic obstructive pulmonary disease (“COPD”). Cempra enrolled four patients in the Phase 2 COPD trial, and shortly after the trial was initiated, three of the patients exhibited patterns of drug induced liver injury (“DILI”), with one patient experiencing clinical hepatitis and another continuing to show symptoms of liver injury even after discontinuation of the treatment. With the liver toxicity data gathered from the COPD trial, Cempra amended the protocol for the Phase 2 NASH trial to reduce dosage from 400 to 200 mg of solithromycin daily, with the option of reducing the dose further to 200 mg three times per week. This amendment was made in consideration of the event that the trials’ patients would experience elevated liver enzymes. Nonetheless, one of the six patients enrolled in the trial with the amended protocol had exhibited a pattern of DILI.

92. On October 16, 2015, Cempra announced positive topline results from its global, pivotal Phase 3 clinical trial of IV solithromycin progressing to oral solithromycin in the treatment of adult patients with CABP. The trial enrolled globally 863 patients with moderate to moderately severe CABP (pneumonia of PORT Class II, III and IV severity classification). The Company reported that in that trial, solithromycin met all pre-defined endpoints for the FDA. In the ITT population (all randomized patients), solithromycin met the FDA primary objective of statistical NI (10% non-inferiority margin) compared to moxifloxacin at early clinical response

(ECR, 72 [-12/+36]) hours after initiation of therapy). The point estimates for the primary endpoint of early clinical response were 79.3% for solithromycin and 79.7% for moxifloxacin. The 95% confidence interval for the treatment difference had lower and upper bounds of -6.1% and 5.2%, respectively.

93. By February 2016, all FDA-required chemistry, non-clinical and clinical trials were complete and work was ongoing for the rolling submission of the NDA, which the Company expected to complete in the first half of 2016. The Company represented that it was preparing to file an application for oral and IV solithromycin for the treatment of CABP with the European regulatory authorities as well, which it also expected to complete in the first half of 2016.

### **Informed Consent**

94. Institutional review boards (“IRBs”), clinical investigators, and study sponsors are required to obtain informed consent from research subjects/patients before treating them.

95. The FDA’s informed consent requirements are set forth in the FDA’s regulations on Protection of Human Subjects, codified at 21 C.F.R. part 50. Subpart B, titled “Informed Consent of Human Subjects,” contains Section 50.20, titled “General Requirements for Informed Consent,” which states the following:

Except as provided in 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights,

or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

96. 21 C.F.R. § 50.25 contains the elements of informed consent, as follows:

(a) *Basic elements of informed consent.* In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) *A description of any reasonably foreseeable risks or discomforts to the subject.*

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) *Additional elements of informed consent.* When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) *A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.*

(6) The approximate number of subjects involved in the study.

97. Beyond being a legal requirement, obtaining informed consent is an ethical necessity for the sponsor and all medical professionals conducting a given clinical trial.

98. As described in further detail below, the Individual Defendants caused the Company to continue clinical trials, without amendment, despite knowing, prior to the end of Phase 3 trials, that patients were subject to dangerously high levels of hepatotoxicity and infusion-related reactions, and this information was not being relayed to patients.

### **The Relationship Between Solithromycin and Ketek**

99. It was expected that the resistance rate for solithromycin for common bacteria would be less than other older macrolides, because bacteria must mutate at three sites in order to become resistant to a drug, as compared to one or two sites for older macrolides. In simpler terms, Solithromycin would purportedly be able to withstand resistance longer than current macrolide therapies and, even if it could not, it would supposedly be one of the only solutions to CABP for the almost 50% of people who have antibiotic resistance. Considering the fact that CABP is the seventh largest cause of death in the U.S., if the FDA were to approve solithromycin, some estimates during the Relevant Period of the Company's sales for the worldwide treatment of CABP were as large as \$2 billion per year.

100. Due to the serious side effects of fluoroquinolones and resistance levels to older macrolides, companies have attempted to develop drugs with macrolide-class safety and fluoroquinolone-like efficacy without the resistance issue. A third-generation macrolide and first ketolide antibiotic called telithromycin, with the brand name “Ketek,” was the first drug to have earned this distinction. The FDA approved Ketek in 2004 as an anti-microbial agent purportedly circumventing antibiotic resistance for CABP, acute bacterial sinusitis, and acute exacerbation of chronic bronchitis. However, shortly after its approval, Ketek was tied to dozens of instances of reversible visual disturbances, a neurological disorder called myasthenia gravis, loss of consciousness, and severe liver injury which resulted in liver failure, liver transplants, and/or death. The issues resulting from the use of Ketek led to two Congressional investigations into the FDA’s approval of Ketek and accusations from insiders that the FDA muffled concerns about Ketek expressed by its own reviewers and dismissed suspicious clinical data later proven to be fraudulent. The investigations consequently led to widespread FDA changes in division leadership and staffing. The FDA and the sponsor for Ketek, Sanofi S.A., agreed on February 12, 2007 to drop two respiratory indications and maintain CABP, which would have a black box warning that noted a high risk of potential liver injuries and contraindicating the drug for certain patients.

101. The Individual Defendants realized that if they were unable to differentiate Ketek from solithromycin, the Company’s revenue-generating ability would be adversely affected, and thus the Individual Defendants touted or caused the Company to tout solithromycin as a drug that was safer than Ketek, as discussed further herein. However, in developing solithromycin, the Company essentially developed the same drug as Ketek except without the elements Cempra claimed were responsible for the side effects of Ketek. As a fluoroketolide, specifically,

solithromycin contains an aminophenyl group with 1, 2, 3-triazole ring, as opposed to Ketek's pyridine attached to an imidazole ring, in order to eliminate the off-target binding to the nicotinic acetylcholine receptors which purportedly caused the serious muscle, visual, and liver problems resulting from the use of Ketek.

### **FDA Reporting Requirements**

102. Due to FDA rules and regulations regarding reporting adverse reactions (e.g., 21 C.F.R. § 312.32(c)(1)(i)(A) and the FDA's Expedited Safety Reporting requirements), Cempra, as a sponsor, was required to promptly report instances of serious adverse events ("SAEs"). The FDA notes that an example of a serious and unexpected suspected adverse reaction that must be reported is a single occurrence of a hepatic injury, since such occurrences are uncommon and known to be strongly associated with drug exposure. The FDA's Expedited Safety Reporting rules note that DILI is the adverse event that most frequently leads to regulatory action on drugs and requires expedited reporting within 15 days of the event. Thus, the Individual Defendants and the Company became aware almost immediately of the solithromycin trials' instances of DILI.

103. Accordingly, at the beginning of the Relevant Period, the Individual Defendants would have been made aware of the occurrences of at least eight patients in the Phase 3 CABP studies experiencing liver toxicity and solithromycin-induced liver injury and, prior to and during the Relevant Period, at least six patients experiencing liver toxicity and solithromycin-induced liver injury during the Company's Phase 1 and 2 studies. These specific occurrences and the surrounding details were not revealed to the public until the 11/2/16 FDA Review (as defined herein).

### **False and Misleading Statements**

104. As described in further detail below, the Individual Defendants made and/or caused the Company to make a series of false and misleading statements during the Relevant Period. The Individual Defendants made or caused to be made affirmatively misleading statements with regard to the impact on the liver resulting from the use of solithromycin, including that: (1) increases in liver enzymes observed were not associated with liver toxicity symptoms and/or injury; (2) during the clinical trials no patients taking solithromycin had experienced liver dysfunction, (3) during the clinical trials Cempra had not seen any reports or data of patients experiencing liver toxicity, and (4) Cempra had not observed any instances of liver toxicity in patients using solithromycin.

105. Moreover, the Individual Defendants also affirmatively made false and misleading statements with regard to solithromycin's superior safety profile as compared to Ketek, specifically noting that in the clinical development of solithromycin, Cempra had not seen any of the liver toxicity issues that had been seen during the Ketek clinical trials.

106. On July 7, 2015, the Company issued a press release titled "Cempra Completes Patient Enrollment of Solitaire-IV Phase 3 Clinical Trail," announcing the completion of patient enrollment for the Company's Solitaire-IV Phase 3 clinical trial of solithromycin in adult patients with moderate to moderately severe CABP (the "7/7/15 Press Release"). In the press release, the Company additionally announced that "[t]op-line efficacy and safety data from this study are expected to be announced by the end of the year." Defendant Fernandes commented on the expectations of top-line results and a "compelling clinical data set in our solithromycin NDA submission," stating, in relevant part:

We remain on track to announce the top line results before year-end 2015. We believe that these results, coupled with our successful Solitaire Oral results, which we announced in January, will provide a compelling clinical data set in our solithromycin NDA submission, expected in 2016. Additional clinical investigations are continuing including a Phase 3 urethritis study, as well as a solithromycin pediatric program.

107. The statements made in the 7/7/15 Press Release were false and misleading, and contained omissions of material fact, because in reality (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

108. On October 16, 2015, the Company issued a press release titled “Cempra Announces Positive Topline Phase 3 Clinical Results for Intravenous Solithromycin in the Treatment of Community-Acquired Bacterial Pneumonia,” noting that elevated alanine transaminase (“ALT”) was observed in both moxifloxacin and solithromycin patients (the “10/16/15 Press Release”). The 10/16/15 Press Release stated, in relevant part, “Treatment emergent ALT elevations were generally asymptomatic, reversible, and not associated with increased bilirubin. No solithromycin patient met Hy’s Law criteria of concurrent ALT and bilirubin elevations post-baseline.”

109. Also on October 16, 2015, the Company held a conference call discussing the IV solithromycin’s positive top-line Phase 3 clinical results. During the conference call, Defendants Fernandes and Oldach engaged in the following exchange with an analyst from Cowen & Company:

[Ritu Baral, Cowen & Company]

Yes. And then the ALT ASG elevations, you mentioned in the press release that they were generally asymptomatic. Where there symptomatic patients in the 3X – or, sorry, Grade 3 or Grade 4?

\* \* \*

[Oldach]

Sure. We've gone through all of these cases and looked carefully at them. There were a few patients, for instance, that had infusion pain but no symptoms relatable to right upper quadrant or liver pain. But we want to be very careful about that. So before we say categorically absolutely none, we will be going back through their cases two more times before we declare that. But generally, no symptoms, no evidence of hepatic injury that was symptomatic or with bilirubin elevation. So that was just a cautionary statement on our part just so we could be absolutely certain. But our impression is none.

[Fernandes]

And remember, the [data management committee] has seen each of these, you know, any significant ALT elevation, during the study and did not do anything.

110. The statements issued by the Company on October 16, 2015 were false and misleading, and contained omissions of material fact, because in reality (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

111. On October 22, 2015, the Company held its earnings call for the third fiscal quarter ended September 30, 2015. During the earnings call, Defendant Fernandes commented on ALT elevations among solithromycin recipients, stating, in relevant part:

Now let's discuss liver safety. Cath studies are conducted in patients with serious disease and underlying comorbidity, meaning they have other bad illnesses. Transient and reversible ALT elevation, which is a liver enzyme increase, is a class-effective macrolide and this is also seen with almost all antibiotic classes, including agents commonly used for CABP, such as augmentin, Rocephin, and the respiratory fluoroquinolones like Avelox and Levaquin.

\* \* \*

As one would expect, in both Phase 3 trials, these we saw some Grade 3 ALT elevation, and to a much lesser extent some Grade 4 ALT elevations. In almost all cases of ALT elevations among solithromycin recipients, these elevations occurred early, peaked on day four – remember, it is day one through seven – and their levels were typically declining by day seven, despite continued study drug dosing. These ALT increases were asymptomatic and resolved post treatment. No solithromycin recipient met Hy's Law criteria, defined as simultaneous ALT and bilirubin elevation – another liver factor – following dosing. There was no evidence of drug hypersensitivity reaction. For instance, one involving a combination of rash, fever, and ALT elevation, and other symptoms.

112. During the same October 22, 2015 earnings call, Defendant Fernandes and David Moore, the Company's former President and Chief Commercial Officer, also commented on the observed ALT elevations, stating, in relevant part:

[Fernandes]

So talking about macrolides and the ALT elevations relative to other macrolides, as you remember in the older study, we just had about the same as Moxifloxacin. And that is about the same as erythromycin and other macrolides. It all depends on the blood levels because as I mentioned, these drugs are excreted, metabolized by the liver. So you get more into the blood. It is going to go most to the liver. You're going to see more ALT increases. Some drugs which don't make much of it in the blood, if they are not absorbed well, you are not going to see much changes. However, this change is expected. Now with the IV, yes, we saw a few more ALT [treat]. But again, they are all reversible. In a real-life situation, unless there is a symptom, unless there is a problem, no one is even going to test it. So when you get Z-Pak, no one takes your blood to see if you got an ALT increase. So the general data is not known. It is only on hospitalization where you would be doing this blood test.

So David, would you like to add anything to that?

[David Moore]

I would just like to underscore the fact that these ALT elevations that we have seen, in

most cases, as Prabha said, have been on their way down with continued dosing by day seven. So we have not seen hepatic dysfunction in any patient due to the study drug in our Phase 3 program.

113. Also during the earnings call, Defendant Fernandes engaged in the following exchange with an analyst from Cowen & Company:

[Ritu Baral, Cowen & Company]

Thanks for taking the question. Just a couple of questions that are related on the topic of the liver enzyme levels. One, can you give us a good idea at this point about how long it generally took for the ALT levels to resolve? Like number of days. And, two: Prabha, if the ALT issue comes up with FDA, from what we understand there, it is mostly associated with the IV dosing as part of the last study. If it ended up being a handicap for the IV formulation, would you consider separating the indications from a regulatory perspective? Could you even do that? How do you look at the oral . . . ?

[Fernandes]

No worries, Ritu. We have had these discussions internally and I don't believe there was any concern at all. But let me address it. Firstly, as I mentioned and David mentioned, most of those ALTs came down during treatment. Many of them were down in two weeks. All of them were down in the three-week visit, the short-term follow-up visit. Okay. So there is no issue with that. So they all disappeared. That is why they are called reversible. And both the oral and the IV study.

114. During the earnings call, Defendant Fernandes also had the following exchange with an analyst from Stifel Nicolaus concerning liver toxicity data:

[Prakhar Verma, Stifel Nicolaus]

This is Prakhar Verma on for Steve today. Thanks for taking my questions. I wanted to ask if there will be any opportunity to provide some further analysis of the liver toxicity data, specifically the kinetics of patient-specific ALT responses over time? Or will we have to wait until you present the entirety of the data next year?

[Fernandes]

We will present a combined data set sometime early next year, but not before a conference. We will certainly do that. But let me again say: there is no liver toxicity. There is no hepatic toxicity. This was reversible ALT elevation and there has been no hepatic toxicity. So there is no evaluation of hepatic toxicity because we don't have any.

115. The October 22, 2015 earnings call additionally contained the following exchange between Defendant Fernandes and an analyst from Ladenburg Thalmann & Company Inc. concerning hepatic toxicity, or the lack thereof, in Ketek's ALT and the Company's ALT:

[Bert Hazlett, Ladenburg Thalmann & Company Inc.]

Thank you for letting me follow up. With regard to just some of the discussions that we have just been having, there has been discussions among investors about potentially comparing solithromycin's activity with the ketolides and [Ketek] in particular. Could you just take a moment or two to describe what you see in terms of ALT elevations with solithromycin compared to what was seen with [Ketek] and what we know about that particular molecule? Thank you.

[Fernandes]

Okay. That question is actually very dear to my heart because we thought we had put it in the coffin and nailed that thing shut a long time ago. But I will address that again.

\* \* \*

What about those ALTs? Now, the ALTs described with [Ketek] was in clinical cases with sinusitis, bronchitis, PORT 1 pneumonia. [Ketek] was never tested in PORT 3, PORT 4 pneumonia. That was not the indication they have been going after. They have been going after community used for upper respiratory tract, not the serious illnesses. It would be unfair to compare ALT enzymes in [Ketek] tech versus our drugs. And I already told you that [Ketek] ALT and our ALT have nothing to do with hepatic toxicity. ALT is not related to hepatic toxicity. And it is found with all drugs, including things like amoxicillin, augmentin, which we are actually giving tons of to children today.

116. The statements made in the October 22, 2015 earnings call were false and misleading, and contained omissions of material fact, because in reality (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and

Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

117. On November 19, 2015, the Company participated in the Jefferies Global Healthcare Conference. During the conference, Defendant Fernandes spoke on the effects and symptoms of solithromycin, stating, in relevant part:

Now when we announced some of the effects of the drug, we did mention liver enzyme increases. ALT increases. And you can see that with the intravenous, we had slightly more ALTs than in the oral, which is listed in the bottom, the Grade 3 and the Grade 4. Now ALTs go up if you had a very good lunch like Jefferies provided this afternoon, I wish I had measured everyone's ALTs because you would've seen ALTs go up in a lot of people. ALTs go up if the liver is a little taxed and is trying to digest and put things out there. And ALTs did go up because we give very high doses of drugs. In antibiotics you always get ALTs go up [sic] in many, many patients because you give high doses of antibiotics either intravenously or orally. And these ALTs go up. With macrolides especially, which are metabolized and excreted by the liver, you will see ALTs go up. And I've seen – I have given you numbers from the 6% with the intravenous azithromycin, which does not have significant blood levels, even with azithromycin, you see up to 6% go up. Now the patients they studied were not sick as our patients because azithromycin is used in minor infections.

\* \* \*

Now the most important things, none of them had any symptoms. They were all reversible, and there was no bilirubin increase in any of these patients. And that is a key point. If you are on this drug, if you don't measure ALTs, you won't even know because there's no symptoms at all, in these patients, and they are all reversible.

Now we have actually put out data of the reversibility. People said, how fast does this reverse? So we have actually posted this data as an 8-K, and if you look at the purple stars on this, we look at the blood levels of ALTs and [aspartate transaminase ("ASTs")] on day one, day four, day seven, and then day 13. And you will see that while on study drugs, the patient is on study drug until day seven, even while on study drug, you can see the ALTs coming down. The liver gets used to it and no longer is it putting out the ALT enzymes.

You can see the same thing with ASTs. This is the reversible ALT and AST increases with no issues, [no] upper quadrant pain, no bilirubin increase and all reversible.

118. During the conference call, Defendant Fernandes also noted that the Company “recorded every single thing the patient said” during the clinical trial, stating, in relevant part:

Now one more hiccup which happened was we talked about intravenous infusion reaction or pain at infusion site. Now you must remember these are very sick patients, and they are getting infusions for CABP. This is a clinical trial. We recorded every single thing the patient said. If there was redness, if there was itching, if there was tingling, anything minor was recorded. And we are an honest company; we put out all the data.

119. The statements made in the November 19, 2015 Jefferies Global Healthcare Conference were false and misleading, and contained omissions of material fact, because in reality (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

120. On January 7, 2016, the Company filed a prospectus supplement on Form 424(b)(5) (the “January Prospectus”) to describe the specific terms of an offering in which it ultimately sold 4,166,667 shares of Cempra common stock for \$24.00 per share, resulting in net proceeds of approximately \$94 million to the Company. With regard to the differences between Ketek and solithromycin, the January Prospectus stated:

Ketek is a macrolide antibiotic that the FDA approved in 2004 for the treatment of multi-drug resistant pneumococci and other CABP bacteria. Soon after release, however, Ketek was found to cause reversible visual disturbances, exacerbate myasthenia gravis (a neurological disorder characterized by improper muscle regulation) and cause liver failure. These effects led the FDA to require the drug label for Ketek to include a strengthened warning section regarding specific drug-related adverse events and contributed to Ketek being withdrawn in 2007 for the treatment of all infections other

than CABP. Through ongoing research, we have developed multiple ways to differentiate solithromycin from Ketek. Our research suggests these side effects may be caused by the pyridine moiety, which forms a part of the structure of Ketek. We have demonstrated that pyridine inhibits the action of nicotinic acid acetylcholine receptors that could result in the side effects caused by Ketek. Solithromycin and older generation macrolides, including azithromycin and clarithromycin, that have been widely marketed do not have a pyridine component. If our research is proven to be incorrect or if solithromycin demonstrates similar side effects, the FDA might not approve solithromycin, or, if already approved, might withdraw approval, require us to conduct additional clinical trials or require warnings on product labeling, which would significantly harm our ability to generate revenues from solithromycin.

121. The statements made in the January Prospectus, which incorporated by reference the July 7, 2015 and the October 16, 2015 press releases (including the false and misleading statements and omissions contained therein), were false and misleading, and contained omissions of material fact, because in reality (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

122. On January 14, 2016, the Company participated in the J.P. Morgan Healthcare Conference. During the conference, Defendant Fernandes downplayed any potential negative side effects of solithromycin, stating, in relevant part:

We would also like to show you some of the ALT results. This is the liver enzyme results. Macrolides that are excreted by the liver and are known to cause liver enzyme increases. You see the label from azithromycin, which is over there, that you see ALT increases. This does not give you the idea that this is hepatic toxic. To have hepatic toxicity, you have to have bilirubin increases, which causes – which shows damage to the liver cells. So, ALT increases plus bilirubin equals what is called [Hy's Law] and that

means liver toxicity. We did not have any case in those numbers which you see there, which had both ALTs as well as bilirubin, not one in those entire two studies.

So, we did not believe we had any side effects of liver toxicity in these particular patients.

I will also point out that they were asymptomatic, so there was nobody who would actually – know in real life during treatment that there was even any ALT increase. What is even more important is the gra[ph] at the very bottom. Even while on study drug, the ALT levels came down. So, if it was toxic, it would not come down, obviously it would stay up. So the liver learned to handle the drug, and then it came down. So we are very pleased with the safety of this as well as the efficacy.

123. The comments made by Defendant Fernandes in the January 14, 2016 conference were false and misleading, and contained omissions of material fact, because in reality (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

124. On February 25, 2016, the Company filed the 2015 10-K with the SEC, signed by Defendants Fernandes, Hahn, Barton, Kong, Goldstein, Johnson, Kent, Neff, Dougherty, and Gill, which commented on the status of the development of solithromycin, stating, in relevant part:

Solithromycin is a potent new fourth generation macrolide and the first fluoroketolide in clinical development. As a macrolide, solithromycin has broad use potential against many types of infections and in many patient populations, including pediatrics and pregnancy. Solithromycin's potency comes from its unique chemical structure, which provides greater ability to fight resistant bacteria. Increasingly, resistance is a major threat to the efficacy of currently available antibiotics, including currently approved macrolides. Solithromycin has excellent organ and tissue distribution and intracellular

activity, which allows it to reach bacteria at body sites that other antibiotics may not. Solithromycin is active against most CABP pathogens, including pneumococcal strains resistant to other macrolides. Our pre-clinical and clinical studies to date have demonstrated solithromycin's efficacy and safety. Solithromycin offers flexibility of dosing, whether IV, oral capsule, or oral suspension which we believe will be attractive to both physicians and patients. These attributes of solithromycin make it a possible treatment for all age groups, including pediatrics.

We have completed two Phase 3 trials for solithromycin which we believe will support our planned new drug application, or NDA, to treat CABP. On January 5, 2015, we announced positive topline results from our global, pivotal Phase 3 clinical trial of solithromycin oral capsules in the treatment of patients with CABP. On October 16, 2015, we announced positive topline results from our global, pivotal Phase 3 clinical trial of IV solithromycin progressing to oral solithromycin in the treatment of patients with CABP. The solithromycin development program was structured through the draft guidance published by and dialogue with the U.S. Food and Drug Administration, or FDA, and also meetings with the FDA. We also have received feedback from several European Union, or EU, member countries regarding our plan to submit a marketing authorization application, or MAA, to the European Medicines Agency, or EMA.

In August 2015, the FDA granted Fast Track designation for IV and oral solithromycin for the treatment of CABP. As a result, we have begun to submit our NDA on a rolling basis as portions of the NDA become ready, rather than waiting for the entire NDA to be completed, which we believe will speed the review time of the NDA. The FDA has designated both oral and intravenous solithromycin as Qualified Infectious Disease Products, or QIDP, for the indication of CABP. As a result of the QIDP designation, solithromycin is eligible for priority review by the FDA. Based on these factors, assuming FDA approval, we expect to be able to launch solithromycin for CABP in 2017. All FDA-required chemistry, non-clinical and clinical trials are complete and work is ongoing for the rolling submission of the NDA, which we expect to complete in the first half of 2016. We are preparing to file an application for oral and IV solithromycin for the treatment of CABP with the EMA, which we also expect to complete in the first half of 2016.

125. The 2015 10-K failed to disclose that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2

studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

126. Attached to the 2015 10-K were certifications pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act, Section 302 of the Sarbanes-Oxley Act of 2002, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, (“Certifications”) signed by Defendants Fernandes and Hahn, attesting to the accuracy of the 2015 10-K.

127. On April 6, 2016, the Company filed the 2016 Proxy Statement with the SEC, providing the following highlights regarding the progress of solithromycin in 2015:

- On January 4, 2015, we announced positive topline results from a global, pivotal Phase 3 clinical trial of solithromycin oral capsules, Solitaire-Oral, in the treatment of patients with community acquired bacterial pneumonia (“CABP”).

\* \* \*

- On August 19, 2015, we announced that the U.S. Food and Drug Administration (the “FDA”) granted Fast Track designation for solithromycin intravenous and capsules for the treatment of CABP.

\* \* \*

- On October 16, 2015, we announced positive topline results from a global, pivotal Phase 3 clinical trial of intravenous to oral solithromycin, Solitaire-IV, in the treatment of patients with CABP.

\* \* \*

- On December 22, 2015, we announced that we successfully completed enrollment of 250 patients in the United States and Australia for our Phase 3 solithromycin trial in urogenital gonorrhea. Additionally, under a Cooperative Research and Development Agreement with the National Institute of Allergy and Infectious Diseases, the Phase 3 trial was expanded to include up to an additional 60 patients, consisting of women and adolescents with culture-proven gonorrhea.

128. The 2016 Proxy Statement was false and misleading, and contained omissions of material fact, because in reality (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

129. On April 13, 2016, the Company participated in the Needham Healthcare Conference, where Defendant Fernandes commented on the differences between solithromycin and Ketek, stating, in relevant part:

Thank you. Yes, we will have an Advisory Committee. Almost surely we will have one. It is a new chemical entity. It's related to a drug called Ketek, so we do expect to have an Advisory Committee, but we have very clearly differentiated solithromycin from Ketek based on its mechanism of action and the reason for its adverse event.

We have also shown the benefit of our drug used in monotherapy up against moxifloxacin, which is not a very safe drug, and we have a very good fully safety package for that. The benefit is obvious, that it needs to have an outpatient as well as hospital drug.

130. The statements made by Defendant Fernandes during the Needham Healthcare Conference failed to disclose that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for

solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

131. On May 1, 2016, the Company issued a press release titled “Cempra Completes NDA Submissions for Solithromycin in the Treatment of Community-Acquired Bacterial Pneumonia” (the “NDA Press Release”).

132. The NDA Press Release announced the completion of the Company’s rolling submission of two NDAs for solithromycin, one for intravenous and one for oral capsules, to the FDA for the treatment of CABP. It also announced that solithromycin was designated by the FDA as a Qualified Infectious Disease Product entitled to expedited consideration, that the FDA granted Priority Review and Fast Track designation for solithromycin IV and capsules for the treatment of CABP.

133. The NDA Press Release stated the following, in relevant part:

CHAPEL HILL, N.C., May 01, 2016 (GLOBE NEWSWIRE) -- Cempra, Inc. (Nasdaq:CEMP), a clinical-stage pharmaceutical company focused on developing antibiotics to meet critical medical needs in the treatment of bacterial infectious diseases, today announced the completion of its rolling submission of the New Drug Applications (NDA) for solithromycin to the U.S. Food and Drug Administration (FDA) for the treatment of community-acquired bacterial pneumonia (CABP). Based on the Qualified Infectious Disease Product (QIDP) designation by the FDA of solithromycin, Cempra has Priority Review and has been granted Fast Track for both the oral capsule and intravenous formulations for the treatment of CABP, which could result in an FDA decision on solithromycin’s NDA within eight months, or by the end of 2016, based on the Prescription Drug User Fee Act (PDUFA) performance goals.

“Completion of the rolling submission of our first NDAs during Cempra’s ten year anniversary year represents a major milestone for the company and a significant step toward our goal of developing antibiotics to meet the critical medical needs of patients in the treatment of bacterial infectious diseases,” stated Prabhavathi Fernandes, Ph.D., president and chief executive officer of Cempra. “We believe the intravenous and capsule formulations will provide dosing flexibility that could lead to fewer hospital admissions, earlier discharge if admitted, and increased treatment of CABP on an outpatient basis. We are confident we have a strong data package for solithromycin.”

“The management of CABP remains a challenge to healthcare professionals and I firmly believe that solithromycin has the potential to be a significant part of the treatment of this life threatening illness, given its published clinical efficacy and potential for multiple formulations,” stated Thomas M. File, M.D., principal investigator for solithromycin clinical trials, Northeast Ohio Medical University. “Solithromycin’s potency, spectrum of activity **and tolerability** could help to offset the rising problem of bacterial resistance, and it is gratifying to note that patients could be closer to benefiting from this potential new treatment.”

The FDA has a 60-day filing review period to determine whether the NDAs are complete and acceptable for filing, and to confirm that Priority Review has been granted. Cempra expects to communicate the agency’s decision regarding acceptance of the NDAs and its PDUFA date when it is known. Cempra’s submissions in the EU remain on track for completion by the end of June 2016.

### About Solithromycin

Solithromycin is a highly potent next-generation macrolide, the first fluoroketolide, which has potent activity against most macrolide-resistant strains. In vitro and in vivo studies have shown potent activity against *S. pneumoniae* as well as an extended spectrum of activity against CA-MRSA, streptococci, Haemophilus, enterococci, *Mycobacterium avium* and in animal models of malaria. It is also active against atypical bacteria, such as legionella, chlamydia, mycoplasma and ureaplasma, and against gonococci and other organisms that cause genitourinary tract infections. It is 8-16 times more potent than azithromycin against many bacteria and is active against azithromycin-resistant strains. Solithromycin’s activity against resistant strains is driven by its ability to interact with three sites on the bacterial ribosome, compared to one for current macrolides. The binding to bacterial ribosomes and interaction with three ribosomal sites is expected to limit the development of bacterial resistance to solithromycin.

134. The statements in the NDA Press Release touting solithromycin’s tolerability were false and misleading, and contained omissions of material fact, because in reality (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and

toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

135. On May 2, 2016, the Company issued a press release to announce that it reported financial results for the quarter ended March 31, 2016 and provided an update on recent corporate developments (“1Q 2016 Press Release”).

136. In the 1Q 2016 Press Release, the Company announced (1) its submission to the FDA of two NDAs for solithromycin for the treatment of CABP, (2) the regulatory review process that the Company expected it to undergo, and (3) various other corporate developments. Specifically, the 1Q 2016 Press Release stated the following, in relevant part:

### **First Quarter 2016 and Recent Corporate Highlights**

- In April, Cempra completed its rolling submission of two New Drug Applications (NDA) to the U.S. Food and Drug Administration (FDA) for solithromycin (intravenous and capsules) in community-acquired bacterial pneumonia (CABP). Having been granted qualified infectious diseases product (QIDP) designation in 2013, solithromycin’s NDAs qualify for an eight month priority review. Subject to approval by the FDA, Cempra plans to launch solithromycin in the U.S. in the first quarter of 2017.
- In March, Cempra received authorization under its existing contract with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, to receive funding of \$25.5 million through mid-2018 for a Phase 2/3 pivotal clinical study of solithromycin in pediatric patients. Cempra is responsible for an additional designated portion of the cost of the planned Phase 2/3 study. Three dosage formulations of solithromycin, intravenous, capsule and oral suspension, will be tested in the trial and may provide pediatricians with greater dosing flexibility.
- In January, Cempra completed a public offering of 4,166,667 shares at a price of \$24.00 per share. Net proceeds after underwriting discounts and commissions and expenses of the offering were approximately \$93.8 million. Cempra intends to use the funds for the commercial launch of solithromycin in CABP in the U.S., subject to the drug receiving FDA approval, and on research and development activities, working capital and general corporate and administrative expenses.

- The Taksta™ (fusidic acid) acute bacterial skin and skin structure infection (ABSSSI) Phase 3 trial is enrolling patients, which is expected to be completed during the first half of 2017.

"I am truly delighted that Cempra is able to mark the tenth anniversary of its founding with our submission to the FDA of two NDAs for solithromycin in community-acquired bacterial pneumonia," said Prabhavathi Fernandes, Ph.D., president and chief executive officer of Cempra. "As a new chemical entity, we expect that solithromycin will be subject to an advisory committee review, however given the compelling data package that we have assembled, we look forward to working with the agency during the review process to bring this important new macrolide antibiotic to patients with CABP and the physicians who treat them. Our development programs for solithromycin for pediatric patients and urogenital gonorrhea, as well our development program for Taksta, are continuing to move forward."

### **Upcoming Clinical Development Milestones**

#### Solithromycin

- Solithromycin pediatric: patient enrollment for Phase 1b trial continues.
- Enrollment in a Phase 2/3 pivotal trial with solithromycin for bacterial infections in pediatric patients is expected to initiate in Q2 2016.
- Phase 3 trial for solithromycin in urogenital gonorrhea is ongoing.
- Phase 2 trial in chronic obstructive pulmonary disease (COPD) is ongoing.
- Phase 2 trial in nonalcoholic steatohepatitis (NASH) is ongoing.
- Completion of the EMA submission for solithromycin in the treatment of CABP is expected by the end of the first half of 2016.

\* \* \*

### **Financial Results for the Three Months Ended March 31, 2016**

For the quarter ended March 31, 2016, Cempra reported a net loss of \$29.4 million, or \$0.61 per share, compared to a net loss of \$17.4 million, or \$0.41 per share for the first quarter in 2015. Research and development expense in the first quarter of 2016 was \$23.5 million, a decrease of 10% compared to the same quarter in 2015. The lower R&D expense was primarily due to the timing of payments for the order of active pharmaceutical ingredient (API) necessary to support the launch of solithromycin as the company begins its commercial readiness activities and a decrease in clinical expenses as the Phase 3 Oral and Phase 3 IV-to-Oral studies are complete. General and administrative expense was \$8.3 million, a 79% increase compared to the quarter ended March 31, 2015,

driven primarily by commercial readiness activities and increased headcount as the company begins to plan for commercialization.

As of March 31, 2016, Cempra had cash and equivalents of \$223.6 million and 48.2 million shares outstanding.

### **Financial Guidance**

The company's current cash and equivalents are expected to be sufficient to fund ongoing operations into the second quarter of 2017, assuming continued timely receipts under the BARDA contract and receipt of expected milestone payments from Toyama. This projection does not include any funds from new financings or partnerships.

\* \* \*

### **About Cempra, Inc.**

Cempra, Inc. is a clinical-stage pharmaceutical company focused on developing antibiotics to meet critical medical needs in the treatment of bacterial infectious diseases. Cempra's two lead product candidates are currently in advanced clinical development. Solithromycin (CEM-101) has successfully completed two Phase 3 clinical trials for community-acquired bacterial pneumonia (CABP) and is licensed to strategic commercial partner Toyama Chemical Co., Ltd., a subsidiary of FUJIFILM Holdings Corporation, for certain exclusive rights in Japan. Solithromycin is also in a Phase 3 clinical trial for uncomplicated urogenital urethritis caused by *Neisseria gonorrhoeae* or chlamydia. Cempra is contracted with BARDA for the development of solithromycin for pediatric use. Three formulations, intravenous, oral capsules and a suspension formulation are in a Phase 1b trial in children from birth to 17 years of age. Taksta™ is Cempra's second product candidate, which is being developed for acute bacterial skin and skin structure Infections (ABSSI) and is also in an exploratory study for chronic oral treatment of refractory infections in bones and joints. Both products seek to address the need for new treatments targeting drug-resistant bacterial infections in the hospital and in the community. Cempra has also synthesized novel macrolides for non-antibiotic uses such as the treatment of chronic inflammatory diseases, endocrine diseases and gastric motility disorders. Cempra was founded in 2006 and is headquartered in Chapel Hill, N.C. For additional information about Cempra please visit [www.cempra.com](http://www.cempra.com).

137. The above statements in the 1Q 2016 Press Release were materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver

injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

138. On the same day, May 2, 2016, the Company filed a quarterly report on Form 10-Q with the SEC for the quarterly period ended March 31, 2016 (the “1Q 2016 10-Q”). The 1Q 2016 10-Q was signed by Defendants Fernandes, Hahn, and Shane M. Barton, the Company’s Controller and Chief Accounting Officer (“Barton”).

139. Attached to the 1Q 2016 10-Q were certifications pursuant to Rule 13a-14(a) and 15d-14(a) of the Exchange Act, Section 302 of the Sarbanes-Oxley Act of 2002, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, (“Certifications”) signed by Defendants Fernandes and Hahn, attesting to the accuracy of the 1Q 2016 10-Q.

140. The Company’s certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (“SOX Certification”), an integral part of the Certifications, contained the following attestations:

1. I have reviewed [the attached filing] of Cempra, Inc.:
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as

defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

- a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

141. The statements above, and in each of the Company's SOX Certifications signed during the Relevant Period (including the above referenced 2015 10-K), were false and/or misleading because the Company's internal control over financial reporting were defective and

were not adequate to prevent the false and misleading statements and omissions of material fact alleged herein.

142. The 1Q 2016 10-Q stated the following, in relevant part:

Our lead product, solithromycin, has completed two Phase 3 clinical trials, for which topline results were reported in January and October 2015. Additionally, we are currently enrolling a Phase 1B clinical trial for solithromycin with pediatric patients. We are developing solithromycin in oral capsules, intravenous, or IV, and suspension formulations, initially for the treatment of community acquired bacterial pneumonia, or CABP, one of the most serious infections of the respiratory tract, for which we recently completed a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA in the second quarter of 2016. Solithromycin is a potent new fourth generation macrolide and the first fluoroketolide in clinical development. We also are conducting a Phase 3 trial of solithromycin in uncomplicated gonorrhea. In September 2015, we began exploring solithromycin's anti-inflammatory properties by initiating Phase 2 studies of solithromycin treating chronic obstructive pulmonary disease, or COPD, and nonalcoholic steatohepatitis, or NASH patients.

143. The above statements in the 1Q 2016 10-Q were materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increase in liver enzymes, including ALT and AST.

144. The 1Q 2016 10-Q also represented the following: "No change to our internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting."

145. The above statement in the 1Q 2016 10-Q was materially misleading because the Individual Defendants knowingly or recklessly omitted that the Company's internal control over financial reporting was defective and was not adequate to prevent the false and misleading statements and omissions of material fact alleged herein.

146. Also on May 2, 2016, the Company held an earnings call discussing Cempra's financial results for the first fiscal quarter 2016. During the earnings call, Defendant Fernandes engaged in the following exchange with an analyst from Leerink Partners and downplayed concerns of liver issues related to solithromycin:

[Paul Matteis, Leerink Partners]

Okay. Thanks, Mark. That's helpful. And then maybe one more for Prabha. I'm wondering what you expect to be the key points of discussion at an advisory committee? I mean, the Phase 3 data, they're clearly positive. You met the FDA end points. So maybe can you speak to any sources of controversy that you expect, if any, and to what degree prior experience with Ketek may play in the discussion at an AdCom?

[Fernandes]

Thank you. So we have worked very hard, together with safety experts, people who have consulted in the past with other companies, with the FDA and so on, very aware of liver safety. We do believe that on the ketek issue, we are over that hurdle, because we have shown the mechanisms as to why ketek was toxic.

However, we do have ALT. So our job is to make a comparison to the older macrolides like [erythromycin], [azithromycin], clarithromycin. All of them do have ALT increases. We have that too. But you must remember that every one of them came down, some of them even – most of them even while on study drug. So we don't believe there is a big concern.

147. The statements made during the May 2, 2016 earnings call were materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with

solithromycin IV, and (3) patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increase in liver enzymes, including ALT and AST.

148. On May 6, 2016, the Company filed a Form 8-K with the SEC, signed by Defendant Hahn, which disclosed a Sales Agreement with Cowen and Company, LLC (“Cowen”), under which the Company was pre-authorized to issue and sell from time to time up to \$150.0 million of its common stock through Cowen as its sales agent (“Cowen Sales Agreement”).

149. In other words, under the Cowen Sales Agreement, the Company was allowed to sell \$150 million worth of Company stock in private placements through Cowen, who was entitled to a commission rate of 3.0% of the gross proceeds from the sales of common stock sold pursuant to the terms of the Cowen Sales Agreement.

150. Through September 30, 2016, the Company sold 4,140,307 shares of common stock under the Cowen Sales Agreement resulting in net proceeds of \$75.1 million after deducting commissions and expenses of \$2.3 million.

151. The same day, May 6, 2016, in connection with the Cowen Sales Agreement, the Company filed a prospectus supplement on Form 424(b)(5) to describe the specific terms of an offering of \$150 million of the Company’s common stock (the “May Prospectus”). The May Prospectus was drafted, reviewed by, and approved by Defendants Fernandes and Hahn.

152. In describing the Company and solithromycin, the Company conveyed in the May Prospectus that there was an unmet need in the treatment of CABP. In furtherance of that point, the May Prospectus contained the following statement:

Despite the many antibiotics available and the size of the market for antibiotics for CABP and other infections, we believe this market has significant critical needs for several reasons. . . . There has not been a new oral antibiotic to treat CABP in outpatients since moxifloxacin was approved, and resistance and lack of tolerability to generic antibiotics, including macrolides, have led to increased rates of hospitalization and a critical need for a safe and effective oral antibiotic for the treatment of CABP. Finally, many of the existing antibiotics used to treat serious infections are difficult or inconvenient to administer, often requiring hospitalization for IV treatment.

153. Presenting solithromycin as a candidate to fill this void of unsafe and intolerable drug products, the Company represented that its “pre-clinical and clinical studies to date have demonstrated solithromycin’s efficacy and safety.” The Company then touted the ease of administration for solithromycin stating that “solithromycin offers flexibility of dosing, whether IV, oral capsule, or oral suspension which we believe will be attractive to both physicians and patients.”

154. The Company then touted its development program, hailing its successful clinical studies and the abidance to regulatory guidelines. Specifically, the Company stated the following:

The solithromycin development program was structured through the draft guidance published by and dialogue with the U.S. Food and Drug Administration, or FDA, and also meetings with the FDA. We also have received feedback from several European Union, or EU, member countries regarding our plan to submit a marketing authorization application, or MAA, to the European Medicines Agency, or EMA.

155. The Company then represented, “we expect the FDA review to be complete by the end of 2016 and to be able to launch solithromycin for CABP in 2017.”

156. Moreover, despite being filed near the end of the first half of 2016, the Company represented that it expected the application for approval of solithromycin to European regulatory authorities to be filed in the first half of 2016.

157. In a section of the May Prospectus describing solithromycin, the Company went a step forward with its representations regarding solithromycin. The Company explained that “[m]acrolide use for serious infections has generally been replaced by fluoroquinolones, despite this class having a less desirable safety and tolerability profile than macrolides,” but the Company “believe[s] solithromycin, with its unique chemical structure, retains and improves on the beneficial features of macrolides and can overcome the shortcomings of existing therapies.” In doing so, the Company was representing that solithromycin was not as susceptible to bacterial resistance as other therapies and *that its safety and tolerability profile was the same, if not better, than existing therapies*. To be sure, the Company listed “oto toxicities” as a limitation of current antibiotic therapies.

158. Indeed, to remove any doubt regarding solithromycin’s safety, the Company assured investors that under FDA guidelines the Company’s phase 3 trials “had to show non-inferiority for efficacy *and acceptable safety and tolerability*.”

159. The Company described the results of the Phase 3 trials, including the occurrence of serious adverse events. Nothing alarming was noted, and solithromycin was reportedly found to be as safe and tolerable as the comparator drugs in the trials. To the extent that the Company noted infusion-related events for solithromycin, the Company brushed them off in claiming that “the majority (over 80%) of [these events] were mild and well tolerated” even though 10 patients discontinued treatment based on infusion-related events.

160. In relation to the Company’s investigation of solithromycin for the treatment of non-alcoholic steatohepatitis (“NASH”), a progressive form of non-alcoholic fatty liver disease, the Company represented that “[s]olithromycin is well tolerated in patients with mild to severe

hepatic impairment and no significant differences in safety, compared to healthy controls, are noted.”

161. The above statements in the May Prospectus were false and/or materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increase in liver enzymes, including ALT and AST. Indeed, the May Prospectus overplayed the safety and tolerability of solithromycin and underplayed the incidence of infusion-related events, misleading investors and the public at large.

162. On May 25, 2016, the Company issued a press release titled, “Cempra Announces Successful Results in the Phase 2 Community Acquired Bacterial Pneumonia (CABP) Trial Conducted by Japanese Partner, Toyama Chemical (a subsidiary of FUJIFILM Holdings Corporation), and containing the headline “*Solithromycin safety and efficacy further validated by Toyama (FUJIFILM)*” (italics in original) (the “5/25/16 Press Release”).

163. The 5/25/16 Press Release announced the results of the Phase 2 CABP trial conducted by the Company’s Japanese partner, Toyama Chemical (a subsidiary of FUJIFILM Holdings Corporation). In the 5/25/16 Press Release, the Company represented that “[o]verall safety and tolerability was similar in both treatment groups, including hepatic events such as increases in alanine aminotransferase (ALT).”

164. Indeed, in the section titled “Safety” the 5/25/16 Press Release quoted Defendant Fernandes and cited her elation with the study results. Specifically, the 5/25/16 Press Release stated the following, in relevant part:

“I could not be happier to receive the results of this important study completed by our strong partner in Japan; ***the safety and efficacy outcomes further validate global Phase 3 trial data*** demonstrating the potential for solithromycin in the treatment of this serious infection,” stated Prabhavathi Fernandes, Ph.D., president and chief executive officer of Cempra. . . . Solithromycin has once again demonstrated robust activity in comparison to a potent fluoroquinolone, levofloxacin, one of the most widely prescribed agents to treat CABP.”

165. The above statements in the 5/25/16 Press Release were false and/or materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increase in liver enzymes, including ALT and AST. Defendant Fernandes’ touting of the “safety and efficacy outcomes” was completely false. This study, and others, really showed a dangerous and unacceptable safety and tolerability profile for solithromycin.

166. On July 5, 2016, the Company issued a press release to announce that its NDAs for the approval of Solithera<sup>TM</sup> (solithromycin) as a treatment for CABP have been accepted for filing by the FDA (the “7/5/16 Press Release”).

167. The 7/5/16 Press Release stated the following:

**CHAPEL HILL, N.C. – July 5, 2016 –** Cempra, Inc. (Nasdaq: CEMP), a clinical-stage pharmaceutical company focused on developing antibiotics to meet critical medical needs in the treatment of bacterial infectious diseases, today announced that its New Drug Applications (NDAs) for the approval of Solithera™ (solithromycin) as a treatment for community-acquired bacterial pneumonia (CABP) have been accepted for filing by the U.S. Food and Drug Administration (FDA). The acceptance of the two NDAs, one for the intravenous formulation and one for oral capsules, indicates the applications are sufficiently complete to permit a substantive review by the FDA.

“The FDA’s acceptance of our two NDA filings brings us one step closer to the potential approval by the end of 2016 and U.S. commercial launch of Solithera,” said Prabhavathi Fernandes, Ph.D., president and chief executive officer of Cempra. “If approved, Solithera would be a significant milestone in the treatment of CABP, as bacterial resistance to older treatments has continued to rise. The FDA will convene a meeting of the Antimicrobial Drugs Advisory Committee for Solithera prior to its action on the applications.”

The NDA submissions are supported by safety and efficacy data from two Phase 3 studies of solithromycin in the treatment of CABP. The first study was a pivotal Phase 3 clinical trial of solithromycin oral capsules, and the second was a global, pivotal Phase 3 clinical trial of intravenous solithromycin progressing to oral solithromycin. Positive topline results were announced for both Phase 3 trials during 2015.

168. Thus, the 7/5/16 Press Release falsely stated that the NDAs would be “supported by safety and efficacy data from two Phase 3 studies of solithromycin in the treatment of CABP.” Indeed, the above statements in the 7/5/16 Press Release were false and/or materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increase in liver enzymes, including ALT and AST.

169. On August 1, 2016, the Company issued another press release to announce the Company's reporting of financial results for the quarter ended June 30, 2016 and to provide an update on recent corporate developments (the "2Q 2016 Press Release").

170. The 2Q 2016 Press Release repeated certain false statements in the 5/25/16 Press Release, including that in the Japanese Phase 2 study of solithromycin "[o]verall safety and tolerability was similar in both treatment groups, including hepatic events such as increases in alanine aminotransferase (ALT)."

171. The 2Q 2016 Press Release quoted Defendant Fernandes as stating, "We remain confident in the data underpinning our NDA and MAA submissions and look forward to working with the regulators to bring the product to the patients who need treatment." Defendant Fernandes was also reported as stating, "Cempra continues to advance its programs successfully and I am excited by the progress we are making with both our clinical development programs and our commercial initiatives as we prepare for the launch of Solithera, subject to approval, early next year."

172. The above statements in the 2Q 2016 Press Release were false and/or materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

173. The same day, August 1, 2016, the Company filed its quarterly report on Form 10-Q for the quarterly period ended June 30, 2016, which was signed by Defendants Fernandes, Hahn, and Barton (the “2Q 2016 10-Q”).

174. Attached to the 2Q 2016 10-Q were Certifications signed by Defendants Fernandes and Hahn attesting to the accuracy of the 2Q 2016 10-Q.

175. The 2Q 2016 10-Q stated, “No change to our internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.”

176. The above statement in the 2Q 2016 10-Q was materially misleading because the Individual Defendants knowingly or recklessly omitted that the Company’s internal control over financial reporting was defective and was not adequate to prevent the false and misleading statements and omissions of material fact alleged herein.

177. Moreover, the 2Q 2016 10-Q was false and/or materially misleading because it omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

178. On September 8, 2016, the Company filed a Form 8-K with the SEC, signed by Defendant Hahn, which attached a PowerPoint presentation that Cempra purportedly used for presentations to investors (the “Corporate Presentation”).

179. The following slides were included in the Corporate Presentation:

### NDAs & MAA Submitted - Potential To Be a Successful Antibiotic

- Solithromycin has completed 2 pivotal Phase 3 trials
- Positive safety and efficacy data from both clinical trials
- Fast Track and Priority review (QIDPs) designations received from the FDA
- Antimicrobial Drugs Advisory Committee meeting on November 4, 2016
- PDUFA Dates: December 27, 2016 (oral), December 28, 2016 (IV)

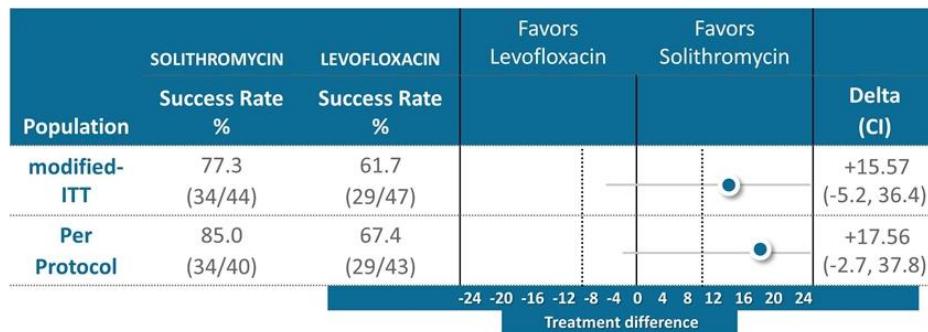


[ 6 ]

cemptra

**Oral Phase 2 Trial in CABP - Toyama**  
*Solithromycin safety and efficacy further validated by Toyama (FUJIFILM)*

*All efficacy outcome measures favored solithromycin*



**Results from recent quantitative Market Research PULM, ID, PCP**

- **What is your current level of satisfaction with current CABP treatments?**
  - 66% Somewhat Satisfied, 17% Very Satisfied
- **If you were told that macrolide resistance to pneumococcus has reached 50%, would you seek an alternative treatment?**
  - 96% Yes
- **Are you concerned with safety of fluoroquinolones (levofloxacin/moxifloxacin)?**
  - 65% Yes

What is needed is a new antibiotic that has the efficacy of a fluoroquinolone but the safety of the macrolide class



180. Thus, the Company continued to represent that clinical studies for solithromycin showed a positive safety profile for the drug, and that a new antibiotic with the “safety of the macrolide class” was needed.

181. The above statements in the Corporate Presentation were false and/or materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

182. On September 12, 2016, the Company participated in the Morgan Stanley Global Healthcare Conference, where Defendant Hahn engaged in the following exchange with an analyst from Morgan Stanley concerning how solithromycin differs from Ketek:

[Andy Berens, Morgan Stanley]

Okay, great. One of the things that some investors have been concerned about is there was a similar macrolide called Ketek that had a pretty sordid past at the FDA. And some people worry that your drug may suffer because of that, both commercially as well as on the regulatory pathway to approval. Can you describe what happened with Ketek and how solithromycin differs?

[Hahn]

Sure. So I'll start and talk about Ketek and some on the regulatory pathway concerns, and then Dave can talk about the commercial opportunity. Ketek was a previous-generation macrolide. It came out between the first generation that Dave talked about and now. And it did have some issues. We've done a lot of work characterizing what caused those issues. And, mechanistically, we looked at the molecule and saw what we think the bad

actor is, and we did a lot of work to identify what that bad actor caused. And it was visual disturbance; it was exacerbation of myasthenia gravis; and it was liver toxicity.

All three were related to this same one bad actor called pyridine. So if we look at solithromycin, we see that solithromycin doesn't have that bad actor on the molecule. It's a completely different structure. And in all of our trials – we have exposed over 2,000 patients and subjects over the years, and nobody has had any of those same types of issues that the folks had experienced with Ketek. So we expect the questions will come up in the AdCom, but we don't – we think that we've adequately addressed those questions and we don't think there will be any issues.

\* \* \*

[Andy Berens, Morgan Stanley]

Okay. Now, in both trials, you saw some elevation of the LFTs. It was all transit. How do you think the FDA is going to address that at the panel? Is that something they will ask the doctors to weigh upon?

[Hahn]

We think they will ask questions about those, most certainly. But we've gone through exhaustive work internally. We've hired independent consultants and advisors. We've got an AdCom advisory, or a consulting firm that brought in panels of experts and have gone through the data. What we see is what you expect from a macrolide: you expect ALTs to go up in the early days, and come back down. Even on continued therapy, we saw the ALT levels coming right back down.

183. During the September 12, 2016 conference, Defendant Hahn also stated, with regard to solithromycin's safety profile, "What we see is what you expect from a macrolide: you expect ALTs to go up in the early days, and come back down. Even in continued therapy, we saw ALT levels coming right back down."

184. The above statements made during the September 12, 2016 conference were false and/or materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had

experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

185. On September 30, 2016, the Company held a conference call discussing interim results for an ongoing study of solithromycin in NASH patients, where Defendant Fernandes commented on ALT increases in the CABP trial, stating, “I will remind you that in our CABP trial, which we presented to you, we have seen ALT increases even during the five to seven days of treatment which comes back.”

186. Defendants Oldach and Fernandes also commented on the change of dosage in a NASH trial during the September 30, 2016 conference call, stating, in relevant part:

[Oldach]

When dosing solithromycin for longer durations, we've observed ALT elevation and since one of the goals of this trial to determine the optimal regimen for longer treatment period, we adjusted the dose to 200 milligrams daily for one week, followed by 200 milligrams three times a week. The lower dose is supported by the mouse model and human PK data that suggest it might be efficacious. We hope to confirm this dosing regimen in the study and we are very excited with the therapeutic effects and safety profile we have seen thus far.

\* \* \*

[Fernandes]

That's why we decided to test it and then thirdly, we also wanted to show that solithromycin, of course, we believe it, is incredibly safe, even in the liver and this is the last straw which breaks the camel's back, right? So we wanted to test it in the worst case situation and tested it and we are now very comfortable with the drug.

\* \* \*

[Ritu Baral, Cowen & Company]

And was this the event [a patient taken off solithromycin in the NASH trial from days 29 to 45 due to ALT elevations] that triggered the change from 200 milligrams daily to the 200 milligrams three times a week in the protocol?

[Fernandes]

No, we had already lowered the dose at that time. Because if you look at the modeling, the long-term dosage and our experience with it is saying that – that was more of a redundant study to show that one would be a long-term chronic dose and if you look at azithromycin, for instance with CF, in multiple doses for many weeks. It's dosed three times a week so it's not unusual for macrolides, which happen to linger intercellularly for long periods of time. That you should reduce the dose of chronic dosing.

\* \* \*

So, Bert, I will remind you that we've seen ALT elevations in our CAB study and again, we knew at the end of this study because we got the results after the study was done. So it was not unexpected that we see it.

\* \* \*

So all of the safety data – every human exposure is submitted as part of the law. We have submitted data until at the end of August and all data comes in, every part will be exposed. And we're very pleased with the safety of the drug. And it will provide a lot of benefits to patients in many categories now and so we're very pleased with it. We're proud to be able to submit this data.

187. The above statements made during the September 30, 2016 conference call were false and/or materially misleading because the Individual Defendants knowingly or recklessly omitted, *at least*, that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

188. On October 27, 2016, the Company issued a press release announcing its operating results for the third quarter ended September 30, 2016 (the “3Q 2016 Press Release”).

189. The Company, in the 3Q 2016 Press Release, discussed the safety and efficacy of solithromycin, but failed to mention that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST. Thus, the statements in the 3Q 2016 Press Release were materially misleading.

190. The same day, October 27, 2016, the Company filed its quarterly report on Form 10-Q for the quarterly period ended September 30, 2016, which was signed by Defendants Fernandes, Hahn, and Barton (the “3Q 2016 10-Q”).

191. Attached to the 3Q 2016 10-Q were Certifications signed by Defendants Fernandes and Hahn attesting to the accuracy of the 3Q 2016 10-Q.

192. The 3Q 2016 10-Q stated, “No change to our internal control over financial reporting occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.”

193. The above statement in the 3Q 2016 10-Q was materially misleading because the Individual Defendants knowingly or recklessly omitted that the Company’s internal control over financial reporting was defective and was not adequate to prevent the false and misleading statements and omissions of material fact alleged herein.

194. Also on October 27, 2016, the Company held an earnings call discussing its financial results for the third fiscal quarter 2016, where Defendant Fernandes engaged in the following exchange with an analyst from Needham and Company concerning ALT increases:

[Danielle Brill, Neeham & Company]

Okay. Great. And then bringing it back to the ad-com and potential topics, obviously Ketek, as you mentioned, has been a concern. Can you just comment on what work was done earlier in development to address these concerns for the FDA?

[Fernandes]

Of course. I didn't plant this question, guys. This one, we've been working for ten years on this, right? So, we started this molecule, Ketek happened, and from day one we had to differentiate it. So, we showed that the pyridine on [telithromycin] was responsible for all those bad adverse events, including the hepatotoxicity.

And the visual effect was really the canary in the coalmine because they saw in all their clinical trials and the same receptor in the eye and the same receptor in the liver, which has caused those effects. And we now have to differentiate the ALT increases that have shown to occur with all macrolides and all antibiotics because of the large dose and show what that is a result of. That is not a Ketek effect. And so we have spent a lot of time doing that sort of work. And our clinical trial data really shows that this has had a great deal of efficacy and all of those ALTs were reversible and asymptomatic, as you remember.

195. The Company and Individual Defendants' statements made on October 27, 2016 were false and misleading in failing to mention that (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, and (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST.

### **The Truth Emerges**

196. On November 2, 2016, two days ahead of the planned FDA advisory committee meeting on solithromycin, the FDA posted a briefing document on its website serving as a preliminary review of solithromycin (“11/2/16 FDA Review”). The 11/2/16 FDA Review revealed shocking news to investors and the public-at-large, including the disclosure that solithromycin safety data showed a significant signal for liver injury and toxicity throughout Cempra’s Phase 1, Phase 2, and Phase 3 clinical studies.

197. The 11/2/16 FDA Review noted that a pronounced hepatic injury signal was seen in the safety databases in the Phase 2 and Phase 3 trials and non-CABP studies, including cholestatic, hepatocellular, and hypersensitivity issues associated with the liver. The 11/2/16 FDA Review also noted that solithromycin’s liver-related adverse events during its clinical development program *exceeded* the pre-marketing hepatic signal seen with Ketek. In fact, the 11/2/16 Review stated that the Company had not presented any evidence to support a claim that solithromycin had a substantially lower potential to cause liver toxicity as compared to Ketek.

198. The 11/2/16 FDA Review also touched on Cempra’s non-CABP studies, disclosing that as a result of patterns of DILI observed in the Phase 2 COPD trial, Cempra had amended its Phase 2 NASH study protocol to a 200 mg daily dosage from the previous 400 mg daily dosage with the option to decrease the dosage to three times a week. Moreover, it was disclosed that the Phase 2 COPD study had been halted pending modification—i.e., a reduction—of dosing as a result of DILI patterns associated with exposure to solithromycin.

199. The 11/2/16 FDA Review further reported that “[a] significant safety signal for hepatotoxicity was observed in the solithromycin development program” and that there was a concern with “the high rate of infusion site-related reactions.”<sup>3</sup>

200. Reuters reported this news and further stated the following, in relevant part:

Solithromycin is descended from a notorious drug made by Sanofi SA called Ketek, or telithromycin, which was approved by the FDA in 2004 but later linked to dozens of serious or fatal liver problems and largely withdrawn.

Cempra constructed the same drug but without the elements it believes were responsible for the side effects associated with Ketek, ***which included visual, neurological and liver problems.*** The company is seeking approval for an oral and intravenous version of solithromycin.

Clinical trials show solithromycin to be as effective as the antibiotic moxifloxacin, the FDA said in its review, but ***rates of liver enzyme elevations were higher in patients treated with solithromycin than with moxifloxacin. High liver enzymes can be a signal of an underlying liver problem, especially if they remain elevated.***

In the Cempra trials enzyme elevations were transitory. Patients did not develop clinical symptoms of liver problems, such as jaundice, and there was no evidence of acute liver damage.

Nonetheless ***the FDA is likely to be especially cautious as the Ketek episode was scarring for the agency. It prompted Congressional investigations and accusations from FDA insiders that the agency stifled concerns over the drug voiced by its own reviewers and dismissed suspicious clinical data that was later shown to be fraudulent.***

“We think the institutional memory of Ketek will force the division into a highly conservative and defensive stance on solithromycin’s safety profile,” Ritu Baral, analyst at Cowen and Company, said in a recent research note.

201. The 11/2/16 FDA Review also included an attached memorandum by Dr. Mark Avigan, Associate Director, Critical Path Initiatives & Hepatologist for the FDA, that analyzed the significant liver safety signal that was associated with solithromycin (the “Avigan Memo”). The Avigan Memo disclosed details regarding at least eight instances of patients taking

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<sup>3</sup> See Toni Clarke, *FDA highlights liver safety issues in Cempra drug review*, Reuters (November 2, 2016), available at <http://www.reuters.com/article/us-cempra-antibiotic-fda-idUSKBN12X1HW> (last accessed November 23, 2016).

solithromycin in Cempra's Phase 3 CABP studies and experiencing liver toxicity and solithromycin-induced liver injury. Per the Avigan Memo, six of the eight patients experienced liver toxicity and liver injury due to use of solithromycin, with the instances of liver injury or toxicity occurring on or about the following dates: April 24, 2014, November 17, 2014, April 9, 2015, May 27, 2015, June 11, 2015, and June 24, 2015. Although the dates of the instances of liver injury or toxicity were not provided for the remaining two patients, they occurred prior to the beginning of the Relevant Period because the completion dates for the two critical Phase 3 CABP studies were in October 2014 and July 2015, respectively. The Avigan Memo additionally revealed that at least six additional patients had suffered from liver toxicity and solithrmycin-induced liver injury during Cempra's Phase 1 and Phase 2 studies, which were either completed prior to the Relevant Period or ongoing during the Relevant Period.

202. On this news, Cempra stock fell \$11.35, or 60.86%, to close at \$7.30 on November 2, 2016, a new 52 week low for the stock.

203. On November 4, 2016, the Company announced that NASDAQ halted trading of the Company's common stock

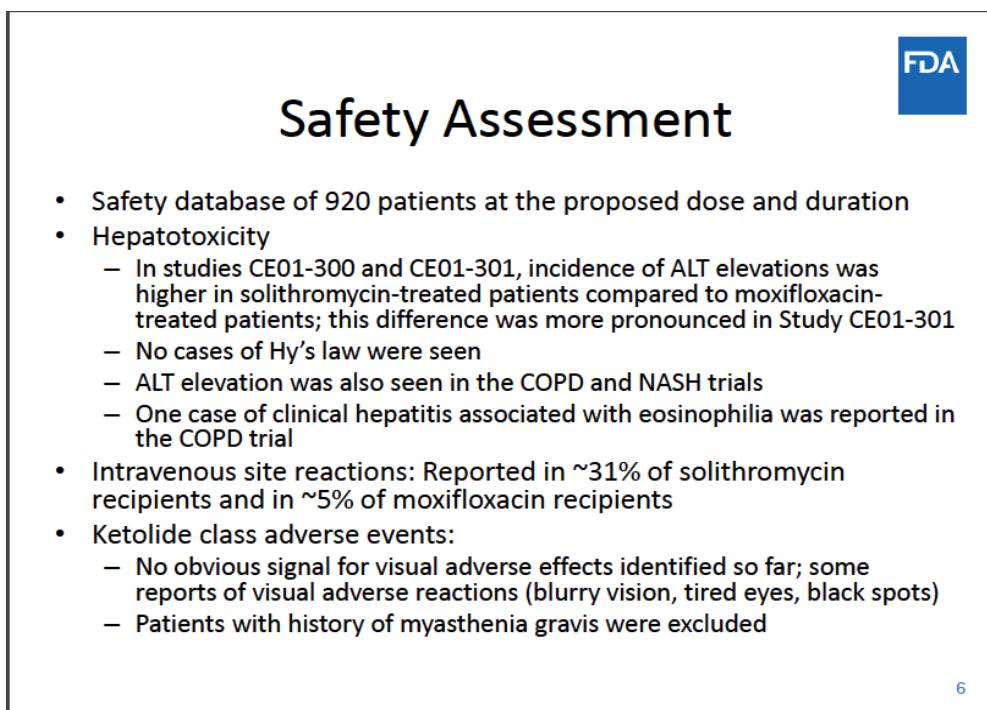
204. Later that day, on November 4, 2016, the Company met with the Antimicrobial Drugs Advisory Committee ("AMDAC") of the FDA to discuss NDA 209006 Solithromycin Capsules and NDA 209007 Solithromycin Injection ("AMDAC Meeting"). The AMDAC Meeting was led by Sumati Nambiar MD MPH, the Director of the Division of Anti-Infective Products, and included remarks and presentations from various FDA officials and representatives.

205. FDA reviewers prepared a background package for the panel members of AMDAC (the "AMDAC Briefing Document"), and the FDA presented its introductory remarks

at the AMDAC Meeting (the “AMDAC Presentation”). Both documents were published by the FDA after the AMDAC Meeting and are publicly available.<sup>4</sup>

206. The AMDAC Presentation was published as a series of 102 slides, covering, in-depth, almost every aspect of solithromycin. The AMDAC Briefing Document was published as a 36-page report with several appendices.

207. The AMDAC Presentation summarized the safety profile of solithromycin in the following slide:



The slide has a blue header bar with the word "FDA" in white. The main title is "Safety Assessment". Below the title is a bulleted list of safety concerns for solithromycin.

- Safety database of 920 patients at the proposed dose and duration
- Hepatotoxicity
  - In studies CE01-300 and CE01-301, incidence of ALT elevations was higher in solithromycin-treated patients compared to moxifloxacin-treated patients; this difference was more pronounced in Study CE01-301
  - No cases of Hy's law were seen
  - ALT elevation was also seen in the COPD and NASH trials
  - One case of clinical hepatitis associated with eosinophilia was reported in the COPD trial
- Intravenous site reactions: Reported in ~31% of solithromycin recipients and in ~5% of moxifloxacin recipients
- Ketolide class adverse events:
  - No obvious signal for visual adverse effects identified so far; some reports of visual adverse reactions (blurry vision, tired eyes, black spots)
  - Patients with history of myasthenia gravis were excluded

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208. At the November 4 meeting, Ramya Gopinath, MD, the Medical Officer in the Division of Anti-Infective Products of the Center for Drug Evaluation and Research of the FDA,

<sup>4</sup> The AMDAC Presentation is available at <http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/anti-infectivedrugsadvisorycommittee/ucm528873.pdf> (last accessed November 23, 2016). The AMDAC Briefing Document is available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM527690.pdf> (last accessed November 23, 2016).

presented the safety concerns with solithromycin for the FDA, and slides presented by her were included in the AMDAC Presentation.

209. In Ramya's portion of the AMDAC Presentation, the FDA presented a series of charts and figures demonstrating that solithromycin potentially contributed to patient death, exhibit higher rates of serious adverse events than its trial comparators, and that infusion-site reactions occurred in 31.3% of patients in the solithromycin arm vs. 5.2% of patients in the moxifloxacin arm.

210. A discussion of hepatotoxicity was addressed in its own section in the AMDAC Presentation. The AMDAC Presentation stated *inter alia* that, with regard to solithromycin, (1) “[d]espite a limited safety database in the Phase 2 and 3 trials (n=920) and the non-CABP studies (n=10), a pronounced hepatic injury signal was seen, (2) “[a] range of hepatic injury patterns - hepatocellular, cholestatic, and hypersensitivity was observed,” and (3) “[i]n 2 subjects in the Phase 3 trials, drug was stopped due to hepatic enzyme elevation.

211. The FDA also showed that because of solithromycin’s structural similarity to telithromycin, the two were expected to have similar effects on the liver – and thus “hepatotoxicity would be expected with the use of solithromycin.”

212. The FDA also analyzed nonclinical studies of solithromycin, which showed hepatotoxicity. In particular, the AMDAC Presentation included the following slide:

# Hepatotoxicity: Nonclinical Studies

- In rats and monkeys, solithromycin is widely distributed to tissues, and with repeated dosing, accumulates in the liver at much higher concentrations than in plasma (liver concentration was 1168x plasma concentration in monkeys after 13 weeks)
- The active metabolites N-acetyl-CEM-101 and CEM-214 account for significant levels of exposure in these animals; in humans, they account for <6% exposure following oral solithromycin administration
- Repeat-dose toxicity studies identified the liver as the primary target organ of toxicity with:
  - Biliary inflammation, centrilobular necrosis/degeneration and death observed in a 4-week oral rat study
  - Weight loss, centrilobular hepatocellular vacuolation, Kupffer cell hyperplasia and moderate increases in AST, ALT and GGT observed in a 13-week oral monkey study
    - Accumulation in lysosomes and phospholipidosis
- Determination of the human equivalent dose (HED) and threshold for toxicity is difficult due to accumulation of solithromycin in the liver and macrophages

[www.fda.gov](http://www.fda.gov)

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213. Indeed, the FDA presented data from Phase 1, 2, and 3 studies of solithromycin showing some degree of hepatotoxicity.

214. This showed that at least during Phase 3 clinical trials, Cempra knew or should have known of hepatotoxicity studies, but did not report such risks to patients when obtaining informed consent, in violation of federal law and industry ethics.

215. In conclusion, the AMDAC Presentation stated the following:

A pronounced hepatic injury signal is observed in a safety database of 920 patients who received a full therapeutic dose of solithromycin for 5-7 days for treatment of CABP

- Clear solithromycin exposure-ALT elevation relationship which appears to be dose- and duration-dependent
- Multiple toxicity patterns – hepatocellular, cholestatic, possible hypersensitivity

- Aminotransferase signal for hepatotoxicity seen with solithromycin in the Phase 3 trials is greater than was seen with telithromycin in Phase 3 trials; telithromycin was associated with severe hepatic injury post-marketing
- Although exploratory computational modeling in DILIsym® may suggest that solithromycin does not have the same mechanism of hepatotoxicity as erythromycin and possibly telithromycin, the high observed incidence of hepatic injury in the relatively small Phase 3 safety database suggests the potential that solithromycin may trigger additional pathways associated with DILI, raising great concern for safety

216. At all relevant times, the Individual Defendants were privy to the same information analyzed by the FDA. Thus, from the AMDAC Presentation alone, it is clear that the Individual Defendants knew or should have known from preclinical, Phase 1, Phase 2, or at the very least Phase 3 studies that solithromycin caused a dangerous level of hepatotoxicity in patients.

217. The AMDAC Briefing Document similarly showed early indicators of hepatotoxicity and infusion-related reactions that informed or should have informed the Individual Defendants of the serious and dangerous toxicity issues with solithromycin and harsh infusion-related reactions.

218. For example, in discussing results from preclinical toxicology studies, the AMDAC Briefing Document stated that “[i]nitial oral repeat-dose toxicity studies in rats and monkeys showed that the primary target organ of toxicity for solithromycin was the liver.” And regarding infusion-related reactions, the same section reported that “[i]n the IV studies in monkeys and dogs (rats were not used for repeat dose IV studies due to unacceptable local tolerance), solithromycin infusion was primarily associated with local lesions at the infusion sites.” The AMDAC Briefing Document also noted that “[a]s with the monkeys, high dose of

solithromycin appeared to exacerbate local infusion site reactions compared with controls and the lower doses (5 and 10 mg/kg).”

219. After discussing the results of the Company’s clinical studies for solithromycin, the AMDAC Briefing Document included a section titled “Evaluation of Safety.” Regarding the safety summary of solithromycin, the AMDAC Briefing Document stated the following:

A significant safety signal for hepatotoxicity was observed in the solithromycin development program. The rates of transaminase elevations were higher in solithromycin-treated patients than those treated with moxifloxacin and were related to solithromycin exposure. The high rate of infusion site-related reactions associated with solithromycin (31.3%) as compared to moxifloxacin (5.2%) is another safety concern.

220. Following the Company’s meeting with the FDA and AMDAC, it issued a press release, on November 4, 2016, announcing that, *inter alia*, the committee “voted (12-1) that the risk of hepatotoxicity with solithromycin had not been adequately characterized and discussed a variety of potential approaches to further characterize the existing liver safety information on solithromycin.”

221. On November 10, 2016, the Company announced the commencement of the first Securities Fraud Class Action:

On November 4, 2016, a securities class action lawsuit was commenced in the United States District Court, Middle District of North Carolina, Durham Division, naming our company and certain of our officers as defendants, and alleging violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by the defendants between May 1, 2016 and November 1, 2016 (the “Class Period”). The plaintiff seeks to represent a class comprised of purchasers of the Company’s common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court.

222. On December 29, 2016, the Company announced in a press release that it had received a complete response letter from the FDA rejecting the NDA for solithromycin in its present form, wherein the FDA noted that the size of the safety database (920 patients) for the

study was “too small to adequately characterize the nature and frequency of serious hepatic adverse effects” and recommended an approximately 9,000-patient exposure study for solithromycin in order to adequately assess its hepatotoxicity profile. The press release additionally noted that “additional clinical safety information and the satisfactory resolution of manufacturing facility inspection deficiencies are required before the NDAs may be approved.”

The press release stated, in relevant part:

CHAPEL HILL, N.C., Dec. 29, 2016 (GLOBE NEWSWIRE) -- Cempra, Inc. (Nasdaq:CEMP), a clinical-stage pharmaceutical company focused on developing antibiotics to meet critical medical needs in the treatment of bacterial infectious diseases, today announced that the company has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) relating to the company's new drug applications (NDAs) for oral and intravenous solithromycin for the treatment of community-acquired bacterial pneumonia (CABP) in adults.

The CRL states that the FDA cannot approve the NDAs in their present form and notes that additional clinical safety information and the satisfactory resolution of manufacturing facility inspection deficiencies are required before the NDAs may be approved.

The FDA did not request any further information on solithromycin efficacy for CABP in the CRL.

Based on their review of the NDAs, the CRL stated that the FDA determined the risk of hepatotoxicity had not been adequately characterized. The FDA noted the size of the safety database is limited to 920 patients who received solithromycin at the proposed dose and duration, and is too small to adequately characterize the nature and frequency of serious hepatic adverse effects.

To address this deficiency, the FDA is recommending a comparative study to evaluate the safety of solithromycin in patients with CABP. Specifically, the CRL recommends that Cempra consider a study of approximately 9,000 patients exposed to solithromycin to enable exclusion of serious drug induced liver injury (DILI) events occurring at a rate of approximately 1:3000 with a 95 percent probability.

The CRL noted that while the FDA reserves comment on the proposed labeling until the NDAs are otherwise adequate, even in the absence of a case of Hy's Law or of another form of serious DILI in future studies, labeling will need to include adequate information about the potential for hepatotoxicity, limiting use to patients who have limited therapeutic options and limitations regarding duration of therapy. A comprehensive plan

for post-marketing safety assessment including an enhanced pharmacovigilance program would also be required.

223. On this news, the price per share of Cempra common stock fell \$3.50, or over 57%, to close at \$2.60 per share on December 29, 2016.

224. On February 28, 2017, the Company issued a press release reporting a loss of \$118 million in 2016 and announcing that its workforce would be reduced from 136 to 45 employees and that it was conducting a review of strategic business options. Moreover, it acknowledged that the Company “is actively engaged in a process to evaluate and assess external late-stage assets and other potential strategic business opportunities to determine the best use of its significant cash resources and clinical programs to deliver value to patients and shareholders through internal and/or potential external opportunities.”

225. On March 13, 2017, the Company issued a press release announcing that Cempra had “retained Morgan Stanley & Co. LLC as financial advisor to the company and to lead its recently announced process to review strategic business options . . . through internal and/or potential external opportunities.”

226. On March 28, 2017, the Company announced that it was withdrawing its marketing authorization application to the European Medicines Agency (“EMA”) which sought approval of intravenous and oral formulations of solithromycin for the treatment of CABP in the European Union. Based on 120 question it received from the EMA, the Company noted that it believed additional data would be required to garner approval in the European Union, and that withdrawal of its application should allow the Company to align its strategy to provide the FDA and EMA with additional data.

227. On June 28, 2017, the Company further signaled that Cempra might cease to be an independent entity and that a strategic transition was forthcoming, announcing in a Form 8-K with the SEC that the Company had entered into change of control severance agreements with Defendants Zaccardelli, Hahn, and Oldach for the purpose of “provid[ing] an incentive to our executive officers to remain with our company before and after any transaction we might pursue. We believe that retaining the knowledge and expertise of our current executive officers, particularly related to solithromycin and our other product candidates and their related clinical trials, is and will be critical to maintaining the value of our company’s assets both while we explore business opportunities and after any such transaction that we might undertake.”

**Defendant Fernandes’ Severance**

228. On December 12, 2016, the Company announced in a Form 8-K filed with the SEC the retirement of Defendant Fernandes as CEO and from the Board, and the appointment of Defendant Zaccardelli as Acting CEO. The Company additionally announced that Defendant Fernandes would continue to serve as a consultant to the Company and that Cempra paid Fernandes a severance payment of \$325,000, consisting of a \$45,000 payment for the waiver of the notice period provided under her employment agreement and an amount equal to her 2016 targeted bonus of \$280,260. Moreover, as part of her retirement, the Company will pay Defendant Fernandes \$420,390, an amount equal to 1.5 times her target bonus over eighteen months, and an amount equal to her monthly salary for eighteen months, at a rate of \$540,000 per year, and her COBRA premium for eighteen months. Even assuming that Defendant Fernandes’ target bonus for 2016 was legitimate—which it was not—her “Target Bonus based upon the average percentage of achievement of target objectives for the prior three (3) years” was not \$280,260 but instead \$93,420. Since 1.5 times \$93,420 is \$140,130, the Board’s

determination that 1.5 times Defendant Fernandes’ “average percentage of achievement of target objectives for the prior three (3) years” was \$420,390 represented a conscious breach of their fiduciary duties.

229. Defendant Fernandes’ is also entitled to accelerated vesting of her unvested stock options upon the conclusion of her consulting services to the Company, unless her consulting services terminate prior to the agreed upon end-date, upon which her stock options will remain outstanding and become exercisable from the end of her consulting period to December 9, 2018, over a year earlier than her outstanding and unvested stock options were originally scheduled to vest. The Board also agreed that upon a “Change in Control” as defined in Cempra’s 2011 Equity Incentive Plain, Defendant Fernandes’ then outstanding and unvested stock options would immediately vest and become exercisable, and all unpaid consulting fees owed to her would immediately become due and payable.

230. Further, Cempra will pay Fernandes \$35,000 per month for up to twenty hours of consulting services per week for one year, which could be extended by mutual agreement. The Board’s approval of Fernandes’ retirement package was purportedly based on Section 10(d) of her Employment Agreement, which gives Fernandes’ the ability to terminate her employment for “Good Reason.” However, Defendant Fernandes’ was not owed anything under the Employment Agreement because her retirement did not meet the criteria for a termination for “Good Reason.” Thus, in stating that the Defendant Fernandes was “entitled to the severance payments and benefits described in Section 10(d) of her employment agreement,” the December 12, 2016 Form 8-K was materially false and misleading. Thus, the Board approved of the Company paying Fernandes over \$1.5 million to leave Cempra, an amount greater than what she would have received if she had terminated her employment for “Good Reason,” despite her overseeing the

misconduct alleged herein, which ultimately led to wasting millions of dollars of the Company's money. The retirement package and benefits awarded to Defendant Fernandes evidenced the Board's breaches of fiduciary duties and constituted a waste of corporate assets and unjust enrichment of Defendant Fernandes.

### **Summary of Defendants' Misconduct**

231. In breach of their fiduciary duties, the Individual Defendants recklessly managed the Company by, in violation of federal law, conducting clinical trials on patients who were not fully informed of the dangerous risk of hepatotoxicity and infusion-related reactions with solithromycin, even though Cempra, the study sponsor, was aware of these risks.

232. In breach of their fiduciary duties, the Individual Defendants failed to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls over financial reporting.

233. In breach of their fiduciary duties owed to Cempra, the Individual Defendants willfully or recklessly made and/or caused the Company to make at least the following false and/or misleading statements and omissions of material fact to the investing public: (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST, and (4) that the Company's disclosure controls and procedures and internal controls over financial reporting were not effective. These facts pertained to the Company's business,

operations, and prospects and were known to the Individual Defendants or recklessly disregarded by them.

234. Additionally, while the Individual Defendants caused the Company's stock to be artificially inflated, two of the Individual Defendants benefitted themselves by engaging in insider sales on material, non-public information.

235. In further breach of their fiduciary duties, the Individual Defendants allowed for Defendant Fernandes to receive an extravagant severance package which was improper in light of her responsibility for the misconduct alleged herein and constitutes waste of corporate assets and unjust enrichment of Defendant Fernandes.

#### **DAMAGES TO CEMPRA**

236. As a direct and proximate result of the Defendants' conduct, Cempra will lose and expend many millions of dollars.

237. Such expenditures include, but are not limited to, legal fees associated with defending the Securities Fraud Class Action filed against the Company and Defendants Fernandes, Hahn, and Oldach, amounts paid to outside lawyers, accountants, and investigators in connection thereto, and losses of revenues caused by customers' loss of trust in the Company's business and products. Additional expenses will be incurred through the undertaking of an internal investigation to implement adequate internal controls over its financial reporting, the losses due to the waste of corporate assets, the losses due to the unjust enrichment of the Individual Defendants who were improperly over-compensated by the Company and who benefitted from the misconduct alleged herein. As a result, Cempra will have to expend many millions of dollars.

238. Such costs include, but are not limited to, compensation, bonuses, and benefits paid to the Individual Defendants who breached their fiduciary duties to the Company.

239. As a direct and proximate result of the Defendants' conduct, Cempra has also suffered and will continue to suffer a loss of reputation and goodwill, and a "liar's discount" that will plague the Company's stock in the future due to the Company's and their misrepresentations and the Defendants' breaches of fiduciary duties and unjust enrichment.

### **DERIVATIVE ALLEGATIONS**

240. Plaintiff brings this action derivatively and for the benefit of Cempra to redress injuries suffered, and to be suffered, as a result of the Defendants' breaches of their fiduciary duties as directors, officers, and/or controlling shareholders of Cempra and unjust enrichment, as well as the aiding and abetting thereof.

241. Cempra is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

242. Plaintiff purchased Cempra common stock in July 2015 and has continuously held Cempra common stock since then. Plaintiff will adequately and fairly represent the interests of Cempra in enforcing and prosecuting its rights and, to that end, has retained competent counsel, experienced in derivative litigation, to enforce and prosecute this action.

### **DEMAND FUTILITY ALLEGATIONS**

243. Plaintiff incorporates by reference and re-alleges each and every allegation stated above as if fully set forth herein.

244. A pre-suit demand on the Board of Cempra is futile and, therefore, excused. At the time of filing of this action, the Board consists of eight Defendants: Neff, Kent, Goldstein, Kong, Johnson, Gill, Dougherty, and Zaccardelli (collectively, the "Directors"). Plaintiff only

needs to allege demand futility as to four of these eight Directors that are on the Board at the time this action is commenced.

245. Demand is excused as to all of the Directors because each one of them faces, individually and collectively, a substantial likelihood of liability as a result of their engagement, either knowingly or recklessly, in the schemes to continue trials on non-fully-informed patients and make and cause the Company to make false and misleading statements and omissions of material fact as described above while they caused investors to overpay millions of dollars for its stock through at-the-market offerings and one of the Directors engaged in insider sales, which renders them unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

246. In complete abdication of their fiduciary duties, the Directors either knowingly or recklessly participated in the conduct alleged herein. The fraudulent schemes were intended to make the Company appear more profitable and attractive to investors. As a result of the foregoing, the Directors breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

247. Additional reasons that demand on Defendant Zaccardelli is futile follow. In addition to serving on the Board, Defendant Zaccardelli is the Company's Acting Chief Executive Officer, and is thus a non-independent director. Defendant Zaccardelli conducted little, if any, oversight of the Company's internal controls over public reporting of financial statements and of the Company's engagement in the schemes described herein, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. Thus, for these reasons, too,

Defendant Zaccardelli breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

248. Additional reasons that demand on Defendant Neff is futile follow. Defendant Neff founded Quaker Partners Management, L.P. (“Quaker Partners”) in 2002 and has since served as a partner at the investment firm. Through a series of entities, Quaker Partners beneficially holds 7.4% of the Company’s stock, and thus Defendant Neff beneficially owns that 7.4% equity plus his own personal holdings. Thus, Defendant Neff has additional incentive to artificially inflate the Company’s stock price; to make Quaker Partners look financially sound and to enhance the reputation of the investment firm. Defendant Neff’s large Company stock beneficial holding, worth about \$95.2 million, reveals his interest in keeping the Company’s stock price as high as possible. Moreover, Defendant Neff has experience on the boards of Companies that committed fraud. He served on the board of directors of Amicus Therapeutics, Inc. (“Amicus”) from 1996 until 2011. That Company has been charged in federal and state court with making materially false and misleading statements regarding clinical trial results and the readiness of the Company to file an NDA. The similarity of the charges in this case and the one against Amicus is more than mere coincidence; and Defendant Neff is the common link. Defendant Neff conducted little, if any, oversight of the Company’s internal controls over public reporting of financial statements and of the Company’s engagement in the schemes described herein, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. In fact, Defendant Neff signed the 2015 10-K and approved Defendant Fernandes’ retirement package. Thus, for these reasons, too, Defendant Neff breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him

is futile and, therefore, excused.

249. Additional reasons that demand on Defendant Kent is futile follow. Defendant Kent holds a degree as a Doctor of Medicine (M.D.) and has served as President and Chief Executive of multiple pharmaceutical companies. Thus, as a maven in the pharmaceutical sciences, Defendant Kent cannot claim ignorance to the dangerously high levels of hepatotoxicity and infusion-related reactions caused by solithromycin because as a director of the Company he was privy to preclinical and clinical trial data, including adverse reaction reports and hepatotoxicity levels in patients. Defendant Kent's large Company stock holding, worth over \$63.64 million, reveals his interest in keeping the Company's stock price as high as possible. Defendant Kent conducted little, if any, oversight of the Company's internal controls over public reporting of financial statements and of the Company's engagement in the schemes described herein, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. In fact, Defendant Kent signed the 2015 10-K and approved Defendant Fernandes' retirement package. Thus, for these reasons, too, Defendant Kent breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

250. Additional reasons that demand on Defendant Goldstein is futile follow. Defendant Goldstein holds a degree as a Doctor of Medicine (M.D.) from Yale University. Thus, as a doctor, Defendant Goldstein cannot claim ignorance to the dangerously high levels of hepatotoxicity and infusion-related reactions caused by solithromycin because as a director of the Company he was privy to preclinical and clinical trial data, including adverse reaction reports and hepatotoxicity levels in patients. Defendant Goldstein's large Company stock holding,

worth about \$32.7 million, reveals his interest in keeping the Company's stock price as high as possible. Defendant Goldstein conducted little, if any, oversight of the Company's internal controls over public reporting of financial statements and of the Company's engagement in the schemes described herein, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. In fact, Defendant Goldstein signed the 2015 10-K and approved Defendant Fernandes' retirement package. Defendant Goldstein's insider sale before the fraud was exposed, which yielded over \$25,318 in proceeds, demonstrates his motive in facilitating and participating in the fraud. Thus, for these reasons, too, Defendant Goldstein breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

251. Additional reasons that demand on Defendant Kong is futile follow. Defendant Kong holds a Bachelor of Science from Stanford University and a Ph.D. from Duke University, and, as the Company explained, was selected for his appointments to the Board based, in part, on his medical training. Thus, as a maven in the sciences, Defendant Kong cannot claim ignorance to the dangerously high levels of hepatotoxicity and infusion-related reactions caused by solithromycin because as Chairman of the Board and a director of the Company he was privy to preclinical and clinical trial data, including adverse reaction reports and hepatotoxicity levels in patients. This is especially true considering that Defendant Kong was a member of the Audit Committee during the Relevant Period. Defendant Kong's large Company stock holding, worth about \$2.9 million, reveals his interest in keeping the Company's stock price as high as possible. Defendant Kong conducted little, if any, oversight of the Company's internal controls over public reporting of financial statements and of the Company's engagement in the schemes

described herein, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. In fact, Defendant Kong signed the 2015 10-K and approved Defendant Fernandes' retirement package. Thus, for these reasons, too, Defendant Kong breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

252. Additional reasons that demand on Defendant Johnson is futile follow. His large Company stock holding, worth about \$2.7 million, reveals his interest in keeping the Company's stock price as high as possible. Defendant Johnson conducted little, if any, oversight of the Company's internal controls over public reporting of financial statements and of the Company's engagement in the schemes described herein, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. In fact, Defendant Johnson signed the 2015 10-K and approved Defendant Fernandes' retirement package. Thus, for these reasons, too, Defendant Johnson breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

253. Additional reasons that demand on Defendant Gill is futile follow. His large Company stock holding, worth about \$2 million, reveals his interest in keeping the Company's stock price as high as possible. Defendant Gill conducted little, if any, oversight of the Company's internal controls over public reporting of financial statements and of the Company's engagement in the schemes described herein, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. In fact, Defendant Gill signed the 2015 10-K and approved Defendant

Fernandes' retirement package. Thus, for these reasons, too, Defendant Gill breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

254. Additional reasons that demand on Defendant Dougherty is futile follow. His large Company stock holding, worth over \$1.6 million, reveals his interest in keeping the Company's stock price as high as possible. Defendant Dougherty conducted little, if any, oversight of the Company's internal controls over public reporting of financial statements and of the Company's engagement in the schemes described herein, consciously disregarded his duties to monitor such controls over reporting and engagement in the schemes, and consciously disregarded his duties to protect corporate assets. In fact, Defendant Dougherty signed the 2015 10-K and approved Defendant Fernandes' retirement package. Thus, for these reasons, too, Defendant Dougherty breached his fiduciary duties, faces a substantial likelihood of liability, is not independent or disinterested, and thus demand upon him is futile and, therefore, excused.

255. In complete abdication of their fiduciary duties, the Directors either knowingly or recklessly participated in the conduct alleged herein. The fraudulent schemes were intended to make the Company appear more profitable and attractive to investors. As a result of the foregoing, the Directors breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

256. Additional reasons that demand on the Board is futile follow.

257. The Directors, as members of the Board, were and are subject to the Company's Code of Ethics. The Code of Ethics goes well beyond the basic fiduciary duties required by applicable laws, rules, and regulations. The Code of Ethics requires all employees, officers and directors to avoid activities or relationships that conflict with the Company's interests or

adversely affect the Company's reputation. The Directors did not comply with the requirements of the Code of Ethics. The Directors violated the Code of Ethics because they knowingly or recklessly engaged in and facilitated the misconduct alleged herein and participated in making and/or causing the Company to make the materially false and misleading statements alleged herein, and whose wrongful conduct resulted in the halting of trading of the Company's common stock on the NASDAQ. Because the Directors violated the Code of Ethics, they face a substantial likelihood of liability for breaching their fiduciary duties, and therefore demand upon them is futile.

258. As members of the Audit Committee, Defendants Dougherty, Gill, and Kong had a duty to review and approve the improper statements described herein. Under the Audit Committee Charter, the Audit Committee is responsible for assisting the Board in overseeing the Company's accounting and financial reporting process. Thus, the members of the Audit Committee were especially responsible for knowingly or recklessly allowing the improper statements related to the Company's financial health, which was dependent on the approval of solithromycin. Moreover, the Audit Committee members reviewed and approved false and misleading statements contained in the aforementioned press releases. With their knowledge or with reckless disregard, the Audit Committee members caused these improper statements to be made. Accordingly, the Audit Committee members breached their fiduciary duties and face a substantial likelihood of liability. Thus, any demand upon the Audit Committee members is futile.

259. The Board additionally permitted the excessive compensation paid to Defendant Fernandes upon her retirement, which constituted a breach of fiduciary duties, waste of corporate assets, and unjust enrichment as to Defendant Fernandes. Accordingly, the Board, particularly

Defendants Kent, Kong, and Neff who comprise the Compensation Committee, breached their fiduciary duties and face a substantial likelihood of liability. Thus, any demand upon them is futile.

260. Defendants Kong, Kent, Gill, Johnson, and Neff are all associated with different venture capital firms, which create many conflicts of interest and entangling relationships that ultimately compromise their independence and disinterestedness. These Individual Defendants placed each other in prominent roles at companies that they were involved with and often simultaneously make investments into the same companies. These entanglements and conflicts of interest raise serious questions as to whether they would vote to initiate litigation against each other. Since venture capitalists compete to fund entrepreneurs, Defendants Gill, Kent, Kong, Johnson, and Neff would be at considerable disadvantages if it became publicly known that they sued one another, or especially Defendant Fernandes, the founder of Cempra, because founders of companies would be less inclined to allow a venture capitalist the opportunity to invest in their respective companies if they knew that they may get sued by them. Due to the reputational harm that Gill, Kent, Kong, Johnson, and Neff's venture capital firms would suffer if they voted to sue each other or Defendant Fernandes, there is a reason to doubt their willingness to actually bring a suit, thereby excusing demand. Moreover, Individual Defendants Gill, Kent, Kong, Johnson, and Neff's participation in the decision to award the lavish retirement compensation to Defendant Fernandes despite her involvement in and primary oversight of the misconduct alleged herein further demonstrates their unwillingness to sue. Thus, demand is futile as to them.

261. The Directors have longstanding business and personal relationships with each other and the Individual Defendants that preclude them from acting independently and in the best interests of the Company and the shareholders. Defendant Kong has known Defendant Kent

since at least 1999, when Kong was a student Duke University and Kent was an Adjunct Assistant Professor of Medicine. Since that time, Defendant Kong has repeatedly placed Defendant Kent on the boards of companies that Defendant Kong invested in through several of his venture capital firms. Defendants Kong and Kent were also both directors of Southeast BIO, a Southeastern U.S. non-profit organization. Defendant Kong also formerly served as Chairman of the board of Serenex, Inc. (“Serenex”), and soon after assuming that position he appointed Defendant Kent as President and CEO of Serenex in November 2002. Defendant Kong also served as General Partner of Intersouth Partners (“Intersouth”) from 2000 to 2010, where Defendant Kent has been a Partner since 2008. In August 2002, Intersouth invested in Serenex, Inc., just before Defendant Kent was appointed CEO Serenex. Soon after leaving Serenex, Defendant Kent became a Partner at Intersouth. Defendant Gill is also tied to Intersouth, which invested in TransEnterix Surgical, Inc. (“TransEnterix”) in 2009, shortly after Defendant Gill became CFO of TransEnterix. Defendant Kong became a director of Intersouth at that time. After leaving Intersouth, Defendant Kong became General Partner of Sofinnova Ventures, Inc. (“Sofinnova”), which invested in Histogenics Corporation, a company where Defendants Gill and Johnson served as directors. Defendant Johnson is Chairman of Strongbridge Biopharma plc, where Defendant Kong is also a director. Defendant Kong is also a director of VirMedica, Inc., where Defendant Johnson serves as Chairman.

262. Moreover, Defendant Goldstein is the managing partner of Aisling Capital, LLC (“Aisling”), which invested in Cempra prior to the Company’s initial public offering. Aisling, like Intersouth, has also invested in TransEnterix. Defendant Gill was the former CFO of TransEnterix and Defendant Kong served as a director of TransEnterix.

263. Defendant Neff is the founding partner of Quaker Partners and a managing member of Quaker BioVentures Capital II, LLC, which is the general partner of Quaker BioVentures II, L.P., which owns 7.4% of the Company according to the 2016 Proxy Statement. Quaker Partners, like Aisling and Intersouth, was an investor in TransEnterix, and made its initial investment in 2009 about the same time Intersouth made an investment. Quaker Partners also invested in Tranzyme, Inc., where Defendant Johnson served as Chairman from 2010 to 2013. These conflicts of interest and entanglements precluded the Directors from adequately monitoring the Company's operations and internal controls and calling into question the Individual Defendants' conduct. Thus, any demand on the Directors would be futile.

264. Furthermore, demand in this case is excused because the Directors, who are named as defendants in this action, control the Company and are beholden to each other.

265. Cempra has been, and will continue to be, exposed to significant losses due to the wrongdoing complained of herein, yet the Directors have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for Cempra any part of the damages Cempra suffered, and will continue to suffer, thereby. Thus, any demand on the Directors would be futile.

266. The Individual Defendants' conduct described herein and summarized above could not have been the product of legitimate business judgment as it was based on bad faith and intentional, reckless, or disloyal misconduct. Thus, none of the Directors can claim exculpation from their violations of duty pursuant to the Company's charter (to the extent such a provision exists). As a majority of the Directors face a substantial likelihood of liability, they are self-interested in the transactions challenged herein and cannot be presumed to be capable of

exercising independent and disinterested judgment about whether to pursue this action on behalf of the shareholders of the Company. Accordingly, demand is excused as being futile.

267. The acts complained of herein constitute violations of fiduciary duties owed by Cempra's officers and directors, and these acts are incapable of ratification.

268. The Directors may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds, i.e., monies belonging to the stockholders of Cempra. If there is a directors' and officers' liability insurance policy covering the Directors, it may contain provisions that eliminate coverage for any action brought directly by the Company against the Directors, known as, *inter alia*, the "insured-versus-insured exclusion." As a result, if the Directors were to sue themselves or certain of the officers of Cempra, there would be no directors' and officers' insurance protection. Accordingly, the Directors cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Directors is futile and, therefore, excused.

269. If there is no directors' and officers' liability insurance, then the Directors will not cause Cempra to sue the Defendants named herein, since, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event, as well.

270. Thus, for all of the reasons set forth above, all of the Directors, and, if not all of them, at least four of them, cannot consider a demand with disinterestedness and independence. Consequently, a demand upon the Board is excused as futile.

## **FIRST CLAIM**

### **Against Individual Defendants for Violations of Section 14(A) of the Securities Exchange Act of 1934**

271. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

272. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that “[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l].”

273. Rule 14a-9, promulgated pursuant to §14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. §240.14a-9.

274. The 2016 Proxy Statement was filed with the SEC on April 6, 2016, and failed to disclose that: (1) a significant safety signal for hepatotoxicity was observed in the solithromycin development program, (2) studies showed a high rate of infusion site-related reactions after injections with solithromycin IV, (3) at least eight patients using solithromycin had experienced liver toxicity and liver injury in the Phase 3 CABP studies of solithromycin and at least six additional patients in the Phase 1 and Phase 2 studies for solithromycin had experienced liver

injury and toxicity—all of whom also experienced significant increases in liver enzymes, including ALT and AST, and (4) that the Company's disclosure controls and procedures and internal controls over financial reporting were not effective. Moreover, the Individual Defendants caused the Company not to correct the 2016 Proxy Statement by amending it with disclosures about the false and misleading statements that were made during the Relevant Period but before the Company's 2016 annual meeting of stockholders, which was held on May 18, 2016. Therefore, the Company's stockholders were misled.

275. In the exercise of reasonable care, the Individual Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2016 Proxy Statement were materially false and misleading at the time it was filed with the SEC and through the time of the annual meeting of stockholders. The misrepresentations and omissions were material to Plaintiff in voting on the matters set forth for shareholder determination in the 2016 Proxy Statement, including but not limited to, election of directors, approval of officer compensation, and appointment of an independent auditor.

276. The Company was damaged as a result of the Individual Defendants' material misrepresentations and omissions in the 2016 Proxy Statement.

### **SECOND CLAIM**

#### **Against the Defendants for Breach of Fiduciary Duties**

277. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

278. Each Individual Defendant owed to the Company the duty to exercise candor, good faith, and loyalty in the management and administration of Cempra's business and affairs.

279. Each of the Individual Defendants violated and breached his or her fiduciary duties of candor, good faith, loyalty, reasonable inquiry, oversight, and supervision.

280. The Individual Defendants' conduct set forth herein was due to their intentional, reckless, or negligent breach of the fiduciary duties they owed to the Company, as alleged herein. The Individual Defendants intentionally, recklessly, or negligently breached or disregarded their fiduciary duties to protect the rights and interests of Cempra.

281. In breach of their fiduciary duties owed to Cempra, the Individual Defendants intentionally or recklessly mismanaged the Company, permitting it to carry-on illegal and unethical practices in conducting its clinical trials.

282. In further breach of their fiduciary duties owed to Cempra, the Individual Defendants willfully or recklessly caused the Company to make false and misleading statements and omissions of material fact. The Individual Defendants failed to correct and/or caused the Company to fail to rectify any of the wrongs described herein or correct the false and/or misleading statements and omissions of material fact referenced, rendering them personally liable to the Company for breaching their fiduciary duties.

283. Additionally, two of the Individual Defendants engaged in lucrative insider sales while the price of the Company's common stock was artificially inflated due to the false and misleading statements of material fact referenced herein.

284. Moreover, the Individual Defendants breached their fiduciary duties by awarding Defendant Fernandes an extravagant severance package and benefits which was improper based on her participation and lack of oversight of the misconduct alleged herein.

285. The Individual Defendants further breached their fiduciary duties by failing to maintain an adequate system of oversight, disclosure controls and procedures, and internal controls over financial reporting.

286. The Individual Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth, in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and omissions were committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of Cempra's securities, obtaining maximal investor funding under false pretenses, and disguising insider sales.

287. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly engage in the fraudulent schemes set forth herein and to fail to maintain adequate internal controls. The Individual Defendants had actual knowledge that the Company was engaging in the fraudulent schemes set forth herein, and that internal controls were not adequately maintained, or acted with reckless disregard for the truth, in that they caused the Company to improperly engage in the fraudulent schemes and to fail to maintain adequate internal controls, even though such facts were available to them. Such improper conduct was committed knowingly or recklessly and for the purpose and effect of artificially inflating the price of Cempra's securities, obtaining maximal investor funding under false pretenses, and engaging in insider sales.

288. These actions were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

289. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Cempra has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

290. Plaintiff on behalf of Cempra has no adequate remedy at law.

### **THIRD CLAIM**

#### **Against Defendants for Unjust Enrichment**

291. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

292. By their wrongful acts, breach of contract, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Cempra.

293. The Individual Defendants either benefitted financially from the improper conduct and received unjustly lucrative bonuses tied to the false and misleading statements, or received bonuses, stock options, or similar compensation from Cempra that was tied to the performance or artificially inflated valuation of Cempra, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.

294. Plaintiff, as a shareholder and a representative of Cempra, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits – including from benefits, and other compensation, including any performance-based or valuation-based compensation, obtained by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.

295. Plaintiff on behalf of Cempra has no adequate remedy at law.

## **FOURTH CLAIM**

### **Against Defendants for Abuse of Control**

296. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

297. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Cempra, for which they are legally responsible.

298. As a direct and proximate result of the Individual Defendants' abuse of control, Cempra has sustained significant damages. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations of candor, good faith, and loyalty, Cempra has sustained and continues to sustain significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

299. Plaintiff on behalf of Cempra has no adequate remedy at law.

## **FIFTH CLAIM**

### **Against Defendants for Gross Mismanagement**

300. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

301. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Cempra in a manner consistent with the operations of a publicly-held corporation.

302. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Cempra has sustained and will continue to sustain significant damages.

303. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

304. Plaintiff, on behalf of Cempra, has no adequate remedy at law.

### **SIXTH CLAIM**

#### **Against Defendants for Waste of Corporate Assets**

305. Plaintiff incorporates by reference and re-alleges each and every allegation set forth above, as though fully set forth herein.

306. As a result of the foregoing, and by failing to properly consider the interests of the Company and its public shareholders, the Individual Defendants have caused Cempra to waste valuable corporate assets by failing to disclose certain risks that impacted the Company's bottom line as alleged herein and by awarding its former CEO an extravagant severance package that was improper in light of her involvement in the wrongdoing alleged herein.

307. As a further result of the foregoing, the Company will incur many millions of dollars of legal liability and/or costs to defend unlawful actions, and to lose assets from investors who no longer trust the Company.

308. As a result of the waste of corporate assets, the Individual Defendants are each liable to the Company.

309. Plaintiff on behalf of Cempra has no adequate remedy at law.

### **REQUEST FOR RELIEF**

FOR THESE REASONS, Plaintiff demands judgment in the Company's favor against all Defendants as follows:

(a) Declaring that Plaintiff may maintain this action on behalf of Cempra, and that Plaintiff is an adequate representative of the Company;

(b) Declaring that the Individual Defendants have breached and/or aided and abetted the breach of their fiduciary duties to Cempra;

(c) Determining and awarding to Cempra the damages sustained by it as a result of the violations set forth above from each of the Individual Defendants, jointly and severally, together with pre-judgment and post-judgment interest thereon;

(d) Directing Cempra and the Individual Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Cempra and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's Bylaws or Articles of Incorporation and the following actions as may be necessary to ensure proper corporate governance policies:

1. A proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the board;

2. A provision to permit the shareholders of Cempra to nominate at least four candidates for election to the board; and

3. A proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations.

(e) Awarding Cempra restitution from the Individual Defendants, and each of them;

(f) Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

(g) Granting such other and further relief as the Court may deem just and

proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: September 15, 2017

**SCHILLER & SCHILLER, PLLC**

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